5

Risk Management and Regulatory Decision-Making

Risk assessment provides only part of the information that risk managers use—with information about public values, statutory requirements, court decisions, benefits, and costs—to make decisions about the need for and methods of risk reduction. Different regulatory goals have engendered different definitions of negligible and unacceptable risk and different roles for risk assessment to play in risk-management decision-making. Risk assessment can provide a valuable framework for setting environmental, health, and safety regulatory priorities and for allocating resources within regulatory agencies. Technical risk assessments seldom set the regulatory agenda, however, because of the different ways in which the nontechnical public perceives risks.

This section examines some of the issues that have arisen as the use of risk assessment in regulatory decision-making has evolved and matured. Characterizing risk and communicating information about risks to affected parties have become complex and confusing. Decisions about how to allocate resources to reduce risks can be made partly on the basis of risk comparisons. The use of "bright lines", benchmarks to distinguish negligible from unacceptable risks, has led to questions about what those lines should be, who should decide what they should be, and which situations they should be applied to. Moving from command-and-control regulation to nonregulatory approaches to risk reduction can increase both efficiency and effectiveness. Peer review of the technical, scientific, and economic information that underlies risk-management decisions can help ensure reasonable, supportable decisions. Judicial review is a common element in major regulatory actions. This section offers recommendations on each of those issues in the hope of contributing to the evolution and improvement of risk-based decision-making.

5.1

Risk Characterization: Communicating and Comparing Risks

Risk communication engages both the communicator and the audience in listening and in explaining information and opinions. Effective risk communication requires effective risk characterization. Risks have sometimes been communicated to the nontechnical public as single numerical estimates, which are easily misinterpreted and misused. Effective risk communication must involve much more than numeric estimates. Risk communication should include clear messages about the nature, severity, and likelihood of risk and other messages, not strictly about risk, that express concerns, opinions, or reactions to risk messages (NRC 1989). Congress has considered various proposals to increase the transparency of risk assessments and to require the use of risk comparisons. Transparency is generally equated with revealing and characterizing the assumptions, uncertainties, default factors, and methods used to estimate risks. Requiring risk comparisons would compel agencies to compare a risk to be regulated with other risks also regulated by the agency and other risks experienced by the public. This section discusses communicating about risk in the risk characterization stage of the risk assessment and other risk communications with the public, including the use of risk comparisons. Section 5.2 discusses comparative risk assessment for risk management, the process of comparing and ranking risks to identify priorities and make resource allocations.

FINDING 5.1.1: Risk characterization is the primary vehicle for communicating health risk-assessment findings. Many risk characterizations have relied primarily on quantitative estimates of risk to communicate risk-assessment findings. Often they convey an unwarranted sense of precision while failing to convey the range of scientific opinion. They are particularly difficult for nontechnical audiences to comprehend. Without effectively communicating information about who is at risk, how they might be affected, what the severity and reversibility of an adverse effect might be, how confident the risk assessors are about their predictions, and other qualitative information that is critical to decision-making, effective risk management is impeded. Risk management is also complicated by the question of how much information is enough. A practical process is needed for determining when risks have been sufficiently well characterized to reach a decision and to justify it.

RECOMMENDATION: Risk characterizations must include information that is useful for all parties participating in a risk-management decision-making process. Quantitative estimates of risk are important and should be included, but qualitative information on the nature of adverse effects and the risk assessment itself is likely to be most useful. Information on the range of informed views and the evidence that supports them also should be shared. During the problem-formulation stage of a risk-management process, participants should agree on criteria for the

value of acquiring additional information so that endless data-gathering does not become primarily an instrument for delaying or obstructing a decision or increasing costs.

RATIONALE

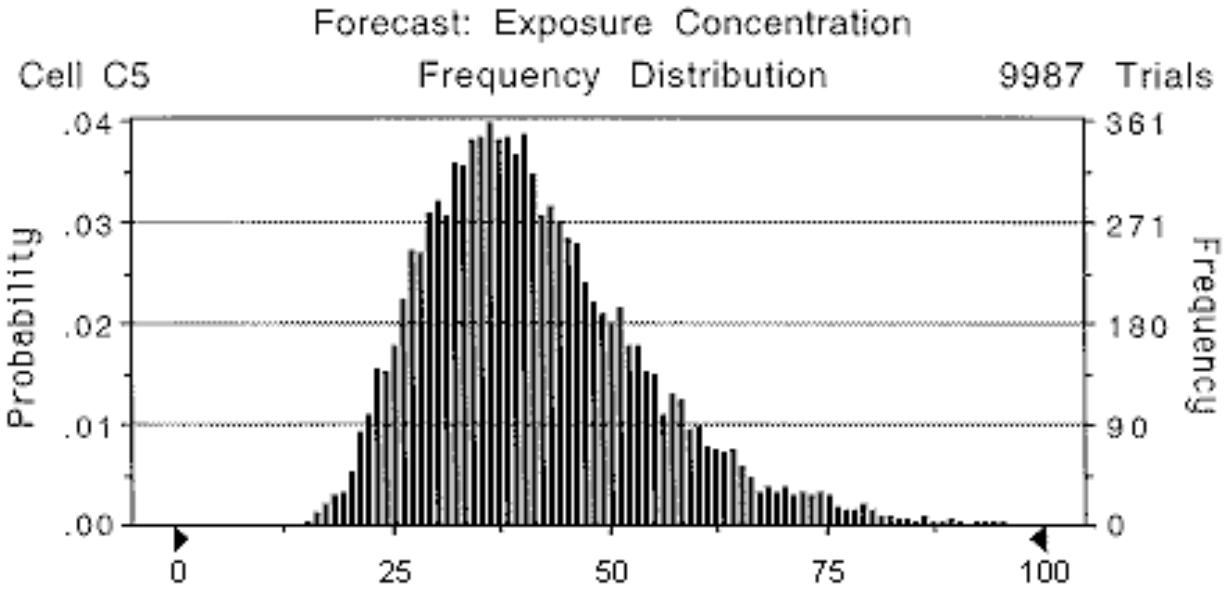
Risk assessment is an uncertain process that requires both scientific data and science-based assumptions. Risk assessments are conducted to infer risks below the range of observable events in people or in studies of laboratory animals. For example, 10-100% of laboratory animals exposed to a relatively high dose of a carcinogen throughout their lives might develop cancers, but regulatory agencies are expected to protect populations from exposure to doses of chemicals that might pose a risk of up to one in a million, not one in 10. The impact of a one-in-a-million cancer risk on a population cannot be detected or measured, because one-fourth of that population is already expected to die of cancer, even in the absence of a particular chemical exposure (see page 3-1). As a result, estimates of small risks are speculative; they cannot be verified. Expressing a small risk solely in numerical terms, especially in single numbers, is misleading and falsely conveys accuracy.

Communicating quantitative information about noncancer risks poses a different challenge because they are not expressed as numerical risk estimates. Noncancer risk is determined by comparing a human exposure to a dose that is considered to be a "safe" standard concentration; that is, exposure to a dose below that standard is considered unlikely to present any risk and exposure just above that standard might be less safe. The quantitative likelihood that adverse effects will occur at exposures above the standard but below exposures observed to cause adverse effects is generally not known. Using a margin-of-exposure approach to cancer risk assessment instead of current methods would result in similar nonprobabilistic expressions of risk (see section 3.1).

More useful and understandable than speculative quantitative estimates of risk is qualitative information. Qualitative information includes a careful description of the nature of the potential health effects of concern, who might experience the effects under different exposure conditions, the strength and consistency of the evidence that supports an agency's classification of a chemical or other exposure as a health hazard, and any means to prevent or reverse the effects of exposure. Qualitative information also includes the range of informed views about a risk and its nature, likelihood, and strength of the supporting evidence. For example, if an agency considers a substance likely to be a human carcinogen on the basis of studies of laboratory animals, but there is some evidence that the classification is flawed, both views should be presented. A discussion of that uncertainty would note the several types of evidence that support the substance's classification as a likely human carcinogen and also the contradictory evidence. The discussion might conclude that because the weight of the scientific evidence supports the substance's classification, the agency has chosen to regulate it as a carcinogen in the interest of protecting public health. Useful guidance for including qualitative information in risk characterizations is found in EPA's Guidance for Risk Characterization (EPA 1995a). Effective ways to communicate quantitative and qualitative information about risks are discussed in more detail below.

As discussed in section 3.3 on uncertainty, communicating a range or distribution of risks reflecting uncertainty is likely to be perplexing to risk managers or nontechnical stakeholders, who often want to know from technical staff whether an exposure is safe or unsafe. There will be complex risk questions that require complex quantitative analysis, but today many risk-management issues are unlikely to be illuminated by intricate quantitative analyses of uncertainty. Federal and state contractors have told the Commission that when they perform comprehensive quantitative analyses of risk-related uncertainty or variability, they are ignored or misunderstood. Of course, as quantitative methods to describe uncertainty and stakeholders' understanding and perceptions of uncertainty and risk evolve and mature, quantitative uncertainty analysis might well attain more general usefulness. Meanwhile, resources would be better spent on conducting research to reduce important sources of uncertainty. As Michael Jayjock, of Rohm and Haas Company, testified before the Commission, "Describing uncertainty is good. Reducing it is better."

In contrast, as discussed in section 3.2, we believe that using distributions to reflect the variability in a population's exposure characteristics can be useful now. Nontechnical stakeholders will certainly comprehend that not all members of a population are exposed to identical doses of contaminants, and that different activities are associated with different exposures. For example, information on toxicity standards could be compared to a distribution of a population's exposures like the following, derived using Monte Carlo techniques and exposure data from a hazardous-waste site.



(μg/m^3)

If the concentration of a chemical associated with a 10^{-5} cancer risk were 80 $\mu g/m^3$, for example, the risk manager and other decision-makers would see that most of the population is exposed to less than that concentration. The participants might decide that there is no cause for concern or might attempt to identify the characteristics of the segment of the population in the upper end of the distribution and consider risk-reduction options directed at that segment. If the concentration of concern were 20 $\mu g/m^3$, participants would see that most of the population is exposed to concentrations exceeding that, and would want to implement more extensive risk-management measures directed at the entire population. The participants might also be interested in comparisons of exposures to contaminant concentrations associated with 10^{-4} or 10^{-6} cancer risks.

Comparing the distribution of a population's exposures to toxicity standards conveys information that is more useful for decision-making than a single point estimate of risk or a hazard index. Priority-setting might not require exposure distributions, but more-refined risk assessments that support decisions with greater regulatory impact would. Comparing the distribution of a population's exposures to a standard or family of standards (see discussion of bright lines in section 5.3) also conveys information to a risk manager that is less complex than a distribution of risks. In contrast with estimated risk levels, exposure standards are concentrations that can be measured; measurements facilitate implementation, evaluation, and compliance. The risk manager and the public can see clearly what the relationship between a protective exposure standard and a particular population's or subpopulation's exposure is likely to be. That information can be used to make decisions about the need for exposure or risk reduction that can be directed at those who are likely to need it most.

A potential barrier to the successful implementation of the Commission's risk-management framework or to the effective use of tiered approaches to risk assessment and priority-setting is conflict over the need for more information. If a simple screening risk assessment performed for the purpose of priority-setting yields results indicating that a particular industrial facility might pose an unacceptable risk, a more refined risk assessment would probably be desired. A more refined risk assessment would require more data than the screening risk assessment, so there would be an incentive for the owner of the facility to generate those data in the hopes that the more refined assessment would show that it does not pose an unacceptable risk. However, if the more refined risk assessment still indicated that the estimated risk is too high, the owner of the facility might decide that collecting even more data would be worth the investment if regulatory action would be deferred. Ellen Silbergeld, representing the Environmental Defense Fund, emphasized in her testimony before the Commission that the greatest barrier to credible risk assessment is the absence of data and that if an iterative approach to risk assessment is required, guidelines are needed for deciding how much information is enough to conclude the process and support a decision. Likewise, Warner North, of Decision Focus, Inc., recommended both incentives for data collection and incentives for speedy risk-management decisions. At some point, continuing to collect and refine will yield considerably diminished returns with respect to improved risk estimation but could effectively stall a risk-management decision that would require capital investment on the part of the facility owner. Before the risk-management decision-making process proceeds, therefore, preferably in the problem-formulation stage, criteria must be established for determining what constitutes enough information. The nature of

the criteria will probably be controversial, but some controversy at the beginning of the process is better than a lot of controversy at the end.

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FINDING 5.1.2: Stories abound of misunderstandings about risks and risk-reduction proposals. We know very little about how to ensure effective risk communication that gains the confidence of stakeholders, incorporates their views and knowledge, and influences favorably the acceptability of risk assessments and risk-management decisions.

RECOMMENDATION: Regulatory agencies should adopt comprehensive risk-communication programs that emphasize both the learning and explaining activities of communication, provide research on risk-communication messages, train risk managers and others engaged in communicating risk, and include risk-communication funding, objectives, and evaluation in risk-management plans.

RATIONALE

The Commission's risk-management framework (section 2) is built on continuous involvement of stakeholders and respectful learning from them. Effective risk communication is an essential ingredient in the success of that framework, especially in the problem-identification and options stages in the process.

Risk assessors now recognize that a community's response to learning that a local industry has put them at risk through release of pollutants tends to include a sense of outrage that inevitably magnifies their perception of risk. Studies of the differences between technical and nontechnical perceptions of risk have identified many of the factors that contribute to outrage (Sandman 1992). Those factors include involuntary exposures, lack of previous knowledge of the risk, and dread of effects and severe consequences (Slovic 1987). People factor in their perceived personal potential benefit and harm. A growing body of research provides some guidance on communicating risk information effectively, as detailed in a report prepared for the Commission by David McCallum (see appendix A.5 for abstract). Our discussion here is not comprehensive; rather, it is intended to indicate the importance of effective risk communication and the potential for mistakes and misunderstandings.

Risk-communication research suggests that people interpret and use new information in the context of their existing beliefs. People need a basic understanding of the exposure, effects, and mitigation processes relevant to making decisions about a hazardous process. Responding to those needs through risk communication should involve well-tested methods; an untested communication should no more be released than an untested product (Morgan et al. 1992). Risk communication is a two-way street, however—it means both listening and speaking. Risk communicators should learn about the concerns and values of their audience, their relevant knowledge, and their experience with risk issues. Stakeholders might have knowledge of sources and patterns of exposure that risk assessors do not have. That knowledge needs to be integrated

into a risk assessment and risk management. The degree to which information provided by stakeholders is incorporated into risk assessment and risk-management decisions may enhance the prospects for trust, a key to effective communication. By listening, risk communicators can craft risk messages that better reflect the perspectives, technical knowledge, and concerns of the audience. Risk communicators must be prepared to explain and answer questions about any specific, relevant tests or surveys done in the community regarding incidences of illness or uptake of pollutants, and not just rely on general models.

Effective communication must begin *before* important decisions have been made, as emphasized in the Commission's framework for risk management. It can be facilitated in communities by citizen advisory panels, such as those supported by the Superfund program and the Department of Energy. Many corporations work continuously with citizen advisory panels in their communities. For example, in his testimony to the Commission, a representative of Rohm & Haas Company, noted that the citizen advisory panels that the company works with give it a better understanding of the questions and concerns of the community and an opportunity to test its risk-communication messages before using them with the general public. Not all citizen advisory panels develop a trusting relationship with the company they are advising or are trusted by the community of which they are a part.

With the growing use of risk assessments and risk estimates by regulatory agencies, there is a need to increase the public understanding and credibility of such information. Agencies and Congress have emphasized the importance of improving the quality of risk assessments but have given less attention to the need for training and educating risk assessors and risk managers in communicating information about risk. Comprehensive risk-communication programs that stress listening, as well as explaining, need to be established in regulatory agencies. Training risk assessors and risk managers in risk communication and testing risk-communication messages should have as high priority as every other part of the risk-management process. Specific communication objectives, such as awareness and involvement of stakeholders, should be identified in risk-management plans, with appropriate methods for evaluating the effectiveness of communication. The National Research Council made the case in *Improving Risk Communication* that "risk managers need to consider communication as an important and integral aspect of risk management" (NRC 1989). A forthcoming Research Council report from the Committee on Risk Characterization also will address the role of stakeholders, especially the public.

The art of risk communication is moving from trying to explain risk information to citizens to a building of partnerships between plant managers and nearby residents, between companies and consumers, and between agency risk managers and the public. Although our air, water, and food are considered cleaner and less risky than they were 30 years ago, the fact that many citizens believe that they are at greater risk indicates that risk communication has a long way to go. Investments of time and resources are clearly needed.

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FINDING 5.1.3: People make informal judgments about risks every day. Some risks are familiar, even comfortable; others are unfamiliar and can be sources of considerable fear. Different people have different perceptions of the same risks. It is logical and reasonable for people to request comparisons or for Congress to incorporate mandates for risk comparisons in legislation. But some comparisons trigger resentment, as though a substantial risk were being dismissed or belittled.

RECOMMENDATION: Risk comparisons should help to convey the nature and magnitude of a particular risk estimate and should compare risks associated with chemically related agents, with the same agent from different exposure sources, with different kinds of agents with the same exposure pathway, or with different agents that produce similar effects. The margin-of-exposure approach (see section 3.1.1) can be applied to such comparisons across similar and different types of adverse health effects.

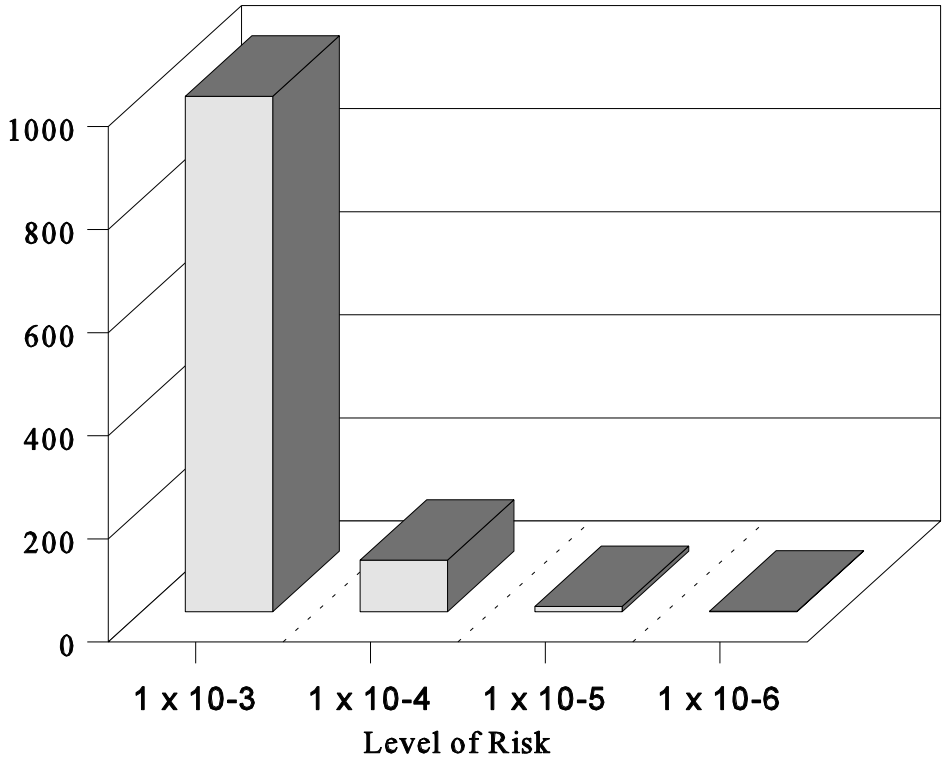
RATIONALE

Risk comparisons can be of many kinds. At the simple end of the spectrum are comparisons of magnitude, such as a one-in-a-million cancer risk compared with the length of one inch in 16 miles; comparisons of chemically related agents, such as one organophosphate pesticide with another; comparisons of the same agent with different exposure sources, such as polycyclic aromatic hydrocarbons from moter-vehicle exhaust and from broiled meat; comparisons of different agents with the same exposure pathway, such as carcinogenic components of natural foods and synthetic additives in food; and comparisons of different agents that produce similar effects, such as the risk of lung cancer from radon inhalation and from smoking a particular number of cigarettes. Toward the complex end, multiple risks are compared across a variety of dimensions, such as the hazards of different energy-producing or Superfund cleanup technologies to the public, workers, and ecosystems.

In general, risk comparisons can help people to comprehend probabilities or magnitudes. Most people, including physicians, often cannot easily relate low-risk probabilities or ratios, such as "one-in-a-million," to their everyday experience. One solution is to make quantitative comparisons between familiar and less familiar risks. A better solution might be to use analogies—one-in-a-million is equivalent to 30 seconds in a year, 1 inch in 16 miles, or 1 drop in 16 gallons. Another solution might be to express risk in terms of the number of persons who might be affected per year or per hypothetical 70-year lifetime. Even more difficult to communicate is the fact that a one-in-a-million risk estimate currently is not an estimate of actual risk, but a statistical upper bound on the likelihood that a risk could exist; that is, the actual risk is likely to be much lower, and it could be zero, but it is quite unlikely to be higher.

Many people perceive the reduction of risk by an order of magnitude as though it were a linear reduction. A better way to illustrate orders of magnitude of risk reduction is shown in Figure 5.1, in which a bar graph depicts better than words that a reduction in risk from one in a 1,000 (10^{-3}) to one in 10,000 (10^{-4}) is a reduction of 90% and that a further reduction to one in 100,000 (10^{-5}) is a reduction 10-fold less than the first reduction of 90%. The percent of the risk that is reduced.

Figure 5.1 Reducing risk by orders of magnitude is *not* equivalent to linear reductions.



by reducing emissions and exposures is a much easier concept to communicate than reductions expressed in terms of estimated absolute risk levels, such as 10^{-5}.

A different proposal for communicating risk magnitude is to use time intervals, which might be better understood than numerical probability estimates. Goldstein indicates that converting probabilities per unit of population to periods per event, such as one death expected in 3,500 years, substantially altered the perception of threat (Weinstein et al. in press). The city of Columbus, Ohio, did an analysis indicating that one death would occur in Columbus in 204 years from an additional cancer risk at the theoretical one-in-a-million level, compared with frequencies of several deaths per day or every few days for measurable risks, such as ordinary rates of heart disease, cancer, homicide, and automobile collisions. The mayor of Columbus, Gregory Lashutka, in testimony before the Commission, stated that that analogy helps citizens to understand the magnitude of the effects that any federal or state regulation concerning the environment, transportation, labor, or education might have on the community. We recommend expressing risks as numbers of events in an actural exposed community or on an annual basis, not just per million hypothetical people over a lifetime.

Using comparisons to explain the magnitude of risks will be increasingly important as advances in analytic chemistry improve our ability to detect smaller and smaller amounts of chemicals in air, water, and other media. This phenomenon of a plummeting "nondetectable" level or a "vanishing zero" poses a problem, particularly in the assessment of risks associated with human carcinogens, to which no level of exposure is assumed to be without risk.

Risk comparisons can be helpful, but they should be used cautiously and tested if possible. There are proven dangers in comparing risks of diverse character, especially when the intent of the comparison is seen as minimizing a risk (NRC 1989). One difficulty in using risk comparisons is that it is sometimes difficult to find risks that are sufficiently similar to make a comparison meaningful. In general, comparisons of unlike risks should be avoided; they have often been either confusing or irritating because they were seen as unfair or manipulative. Research on risk perception has suggested that directly comparing voluntary and involuntary risks or natural and technologic risks does not improve understanding of risks. However, comparisons of risks associated with chemically-related agents, risks associated with the same agent with different exposure sources, risks related to different kinds of agents with the same exposure pathway, or comparisons of different agents that produce similar effects can improve communication.

Risk comparisons can either improve or hinder risk communication. Testing messages that use risk comparisons, even informally, can help to avoid miscommunication and misunderstanding.

5.2

Comparative Risk Assessment for Risk Management

Priority-setting is necessary when money, time, and staff are limited. The Carnegie Commission on Science, Technology, and Government, the National Academy of Public Administration, many members of Congress, and Supreme Court Justice Stephen Breyer have recommended comparative risk-assessment approaches for priority-setting.[1] The comparative-risk process includes a variety of tasks, from problem identification, data collection and analysis, and risk ranking of environmental problems to developing an action plan and implementing new strategies for risk management and reducing risk. Most of the comparative-risk projects for priority-setting have been initiated by state, local and tribal governments and typically by one or more of the environmental protection, natural-resource, or health agencies. Our recommendation here is directed at federal agencies.

FINDING 5.2: Federal regulatory agencies are confronted with many problems and issues related to health and environmental protection, but have limited time and resources for action. The risks associated with the problems and the resources available to act on them are often misaligned. State, local, and tribal comparative-risk projects have been useful in addressing such mismatches and in refining the comparative risk process to better manage risks.

RECOMMENDATION: Agencies should use a comparative-risk assessment approach for risk-management on an experimental or demonstration basis to test the effectiveness of seeking consensus on setting priorities for environment, health, and safety hazards. The priorities, reflecting diverse stakeholder values and opinions, should influence agency resource-allocation decisions.

RATIONALE

The Environmental Protection Agency (EPA) undertook some of the earliest efforts to use comparative risk assessment to rank environmental risks and set priorities for agency efforts. In 1987, EPA staff prepared a report, *Unfinished Business: A Comparative Assessment of Environmental Problems* (U.S. EPA 1987b), that identified risks receiving in their view inadequate attention from the agency. An important conclusion of the report was that the EPA's program priorities tended to reflect the public's perception of risks, rather than the most serious risks as judged by EPA scientists and staff. The Science Advisory Board reviewed that report and issued *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* (SAB

[1] Section 5.1 of this report considers comparisons of specific risks for the purpose of communicating about risk.

1990). The Science Advisory Board emphasized the subjective nature of rankings and called for broad public participation in ranking environmental risks so that risk reduction policies based on imperfect and evolving scientific understanding and subjective public opinion would be supported widely. In 1995, EPA and Congress asked the Science Advisory Board to undertake an integrated ranking project as a follow up to the risk rankings in *Reducing Risk*. The difference in those efforts and the EPA-funded state, local, and tribal comparative-risk projects is the explicit incorporation of public values and perceptions of risk, a process of diverse stakeholder involvement, and inclusion of elected-officials' representatives in the state, local, and tribal activities. As a result, it appears that the state, local, and tribal comparative risk assessment projects might have been more successful in influencing agency priorities and resource allocations. Unfortunately, Congressional proposals to institute comparative risk assessment reports by federal agencies along with appropriate adjustments in budget requests have not reflected the experience and enhanced understanding of the role of public values in priority-setting gained from the state, local, and tribal comparative risk assessment for risk management projects.

Comparative risk assessment for priority-setting brings together science and public values by making clear what is known and what is not known about the environmental challenges we face. The comparative-risk process includes organizing teams of agency and nonagency stakeholders, such as representatives of business and environmental groups; making a comprehensive list of environmental problems; assembling the available good information about the sources of the problems and the risks that they pose to human health, ecosystems, and quality of life; ranking the problems in order of the group's view of the risks posed; and using the rankings to guide strategic planning and budgeting. Methods for ranking the risks of identified problems have included: voting by participants, formulas that rely more heavily on quantitative data, matrix-based discussions that use graphics in a shared decision-making process, decision-seeking consensus, and bargaining or tradeoffs among stakeholders. That approach to comparative risk assessment for risk management tracks the six steps of the Commission's risk-management framework (see section 2) and can mobilize and energize stakeholder participation.

Each federal agency will need to adapt the fundamental elements of the comparative-risk ranking approach to its mission, statutory mandates, and current and emerging responsibilities. At the federal level, agencies can substitute Congressional staff of authorizing committees of Congress for state and local representatives and can identify as participants internal agency and affected stakeholders on the basis of programs and projects of specific agencies. Depending on the agency, it will be important to include representatives from state, local, and other federal agencies with relevant programmatic responsibilities or interests. State and local participation will be especially important as roles and obligations change under the Unfunded Mandates Act of 1995, which places limits on the capacity of the federal government to implement new programs that will cost state and local governments over $50 million in any year.

Benefits other than priority-setting often justify putting time and effort into the comparative-risk assessment process for priority-setting (Minard and Jones 1993). Most comparative-risk projects produce a catalog of the major environmental problems facing a state or locality, which can be a

valuable resource for the public and for risk managers. Participants in a comparative-risk project learn about a range of problems that might not be part of their daily interests or responsibilities. The comparative-risk process improves understanding of competing priorities, provides an appreciation of the complexity of decision-making, and can stimulate new insights into solutions. As a result of increased communication among institutions and interest groups, new avenues of cooperation might be established. Adversarial relationships among interest groups and jurisdictional conflicts among agencies might not disappear, and could even be intensified, but comparative-risk projects have revealed unexpected agreement among parties and enhanced understanding of differences in perspectives and values in some cases. Most important, experience has shown that the process itself can help to build coalitions that favor priority setting and shifting resources to the identified priorities. Broader public support for a common agenda might allow agencies, state legislatures, and Congress to move money and staff into priority problems with less litigation and less controversy. In fact, Charles Kleeburg, director of the Seattle Drainage and Wastewater Utility, explained to the Commission that the city's success in forging consensus on 10 priority problems that were acted on by the city government was a direct result of the influence and effectiveness of the comparative risk assessment process. In contrast, testimony from EPA indicated that a great deal of controversy is generated when it tries to address problems that it knows are real, but has not been told by Congress to address.

There are a number of challenges to and limitations to the usefulness of the process as pointed out by Patricia Buffler and Carl Craner, in their testimony before the Commission about the California Comparative Risk Project. For example, there is no guarantee that the process will produce consensus among stakeholders, agencies, and funding authorities. Resolving inconsistent data across problems, forcing all risks into a common measurement, and integrating problems into a single list are important methodologic challenges. The degree of uncertainty varies across problems, making comparisons difficult. The process might not adequately account for environmental equity, emerging issues, and effects across jurisdictional boundaries. Those problems can result in some groups' objecting strongly to the rankings, in loss of opportunities for preventing future risks, and in the neglect of risks imported from or exported to other geographic areas. Lack of sufficient resources and time constraints can limit data collection, diminish the quality of data analysis, and hinder development of risk-management strategies and recommendations. For federal agencies, there may be additional problems of having to propose changes to statutory mandates when priorities for resources change and the difficulty in taking action in the absence of clear or explicit statutory direction.

The comparative-risk process emerging from the state, local, and tribal projects supported by EPA constitutes a worthy starting point for federal agencies to use in ranking priorities and making resource-allocation decisions. For example, the risk-based process being introduced by the Department of Energy's Environmental Management Program at the nation's nuclear-waste sites is testing how well identification, analysis, and comparison of risks and remedies can be translated into budget decisions. The Commission encourages federal regulatory agencies to use comparative risk for priority-setting on an experimental or demonstration basis.

5.3

Bright Lines

A "bright line" is a single numerical value between unacceptable and negligible magnitudes of risk or exposure concentrations of concern. Bright lines are chosen to provide pragmatic definitions of "safe" and "unsafe" for those making risk-management decisions and for those implementing or enforcing decisions. An example of a bright line is an excess-cancer risk of about 10^{-5}: if a risk assessment predicts that more than one case of cancer is likely to occur as a result of exposure to a substance in a population of 100,000 people exposed to it, that risk is judged unacceptable and protective action is required; a predicted risk of less than 10^{-5} is considered negligible and requires no protective action. Risk-based decisions are generally converted to measurable exposure or emission limits for implementation and compliance. Regulated parties are expected to demonstrate that estimated exposures or risks are below the bright line to operate a manufacturing facility, introduce a new product to the market, or sell foods with low concentrations of contaminants.

Bright lines are generally used with single point estimates of risk to judge safety; *Science and Judgment in Risk Assessment* characterizes bright lines and point estimates of risk as "magic numbers" whose use is inconsistent with knowledge about the distributions of risk and their inherent uncertainty (NRC 1994a). Strict use of bright lines is also inconsistent with the risk-management framework and with the inclusion of cost and other considerations in decision-making. Bright lines that are health-based standards provide useful goals, however, to guide a decision-making process.

FINDING 5.3: Risk managers have often relied on clearly demarcated bright lines, defining boundaries between unacceptable and negligible exposures or risks, to guide their decisions. Congress has occasionally sought to include specified bright lines for risk in legislation. However, a strict bright-line approach to decision-making cannot explicitly reflect uncertainty about risks, population variation in susceptibility, community preferences and values, or economic considerations, all of which is required by the Commission's risk-management framework.

RECOMMENDATION: Bright lines or ranges of bright lines should be used as guideposts or goals for decision-making but should not be applied inflexibly. In addition to bright lines intended to protect the general population, bright lines to protect especially susceptible subpopulations—such as young children, pregnant women, or adults with lung disease—should be considered. Congress should leave the establishment of specific bright lines or ranges of bright lines to the regulatory agencies.

RATIONALE

Risk managers are accustomed to the clear guidance provided by bright lines for implementing and determining compliance with risk-based standards or guidelines. Measurable contaminant concentrations—such as permissible exposure limits (PELs) or threshold limit values (TLVs) in the workplace, action levels for food contaminants like aflatoxin on peanuts or mercury in swordfish, and national ambient air quality standards (NAAQS) for carbon monoxide or ozone in air—provide assurance that risks will be negligible as long as contaminant exposure concentrations are below the bright lines of those values. If risks or contaminant concentrations are found to exceed their bright lines, action is expected to be taken to protect workers, consumers, or the community. Small quantitative differences from those lines, whether above or below, can make a big difference in whether protective actions are taken. Nonetheless, bright lines provide a basis for consistent decision-making.

There are several potential problems in the use of specified bright lines. Bright lines are burdened by all the uncertainty, variability, and assumptions inherent in risk estimation; thus, the all-or-nothing nature of use of a bright line could be misunderstood and construed to imply that there is an exact boundary between safety and risk. Risk assessments themselves can be manipulated so that their results emerge above or below the bright line according to a risk manager's particular policy preferences. Bright lines have the potential to be applied inflexibly, leading to decisions that do not reflect the unique characteristics of particular populations. Implementing the Commission's risk-management framework will require the consideration of bright lines as a source of information about risk that is useful in the decision-making process, but they would not be the sole determinants of the outcome of that process. Roger Pryor, executive director of the Missouri Coalition for the Environment, testified before the Commission that although bright-line standards should be established on the basis of health considerations, other factors, such as cost and the role of cultural differences, should also play a role in risk-management decisions.

Congress has included bright-line risk provisions in several legislative bills in recent years. Not until the 1990 Clean Air Act Amendments, however, did Congress pass legislation specifying a quantitative risk, when it mandated the development of a strategy for evaluating residual risks after maximum available control technology (MACT) implementation based on an incremental lifetime cancer risk of 10^{-6}.

Bright lines have been well established by regulatory policy despite their absence in legislation. For example, the Food and Drug Administration regulates intentional and unintentional additives in food by calculating an "estimated daily intake" and comparing that value to a previously established "acceptable daily intake". When the ratio exceeds 1.0, the agency considers the exposure unacceptable (Flamm and Lorentzen 1988). Noncancer health effects are evaluated similarly under Superfund; contaminant doses are compared to bright-line values called reference doses. If the ratio is less than 1.0, adverse effects are considered unlikely, and no action is required.

Ranges of bright lines have also been adopted by regulatory policy. For example, under Superfund, a pair of bright lines has been used to define a potentially acceptable risk range for carcinogens. A contaminated site is considered to pose a negligible risk if a risk assessment of the site produces an upper-bound lifetime incremental cancer risk estimate not exceeding 10^{-6}. The site is considered to pose an unacceptable risk, requiring remediation, if the risk estimate is 10^{-4} or higher. Between 10^{-6} and 10^{-4}, remedial actions, if any, are determined case by case.

In addition to ranges of bright lines, multiple bright lines should be considered. For example, section 3.1.3 discusses the need to consider sensitive subpopulations in risk assessments. The results of such risk assessments might be expressed in terms of an estimated risk for the general population and a different estimated risk for a sensitive subpopulation. Those risk estimates could be used to establish a bright line for the general population and a different bright line for the sensitive subpopulation. Decisions about appropriate levels of risk reduction could then be made with the benefit of the knowledge of those differences. EPA's deputy administrator, Fred Hansen, noted in his testimony before the Commission that getting away from single bright lines would be consistent with incorporating environmental justice considerations into risk management.

Bright lines expressed as contaminant concentrations are easier to implement than bright lines expressed as risks.[1] Although concentration-based bright lines are derived from some judgment about what exposure constitutes negligible risk (or, in some cases, technologic feasibility), risk managers or compliance officers can easily determine whether they are being adhered to because concentrations can be measured. When bright lines are expressed as risks, uncertain and variable risk estimates must be compared to determine compliance. Comparing risks will become even more difficult as distributional approaches to risk estimation are implemented.

[1]Examples of bright lines based on contaminant concentrations are maximum contaminant levels (MCLs) for drinking water, which, although derived from some estimate of risk, can be easily measured and therefore enforced. Expressing MCLs in terms of risk would be more difficult to enforce because risks would have to be estimated from contaminant concentrations and other variables at each drinking-water source; this would be a cumbersome and uncertain way to determine compliance.

5.4

Alternatives to Command-and-Control Regulation

In the last quarter-century, the United States has made extraordinary progress in environmental protection as a result of substantial investments by governments and by industry and through effective public and political advocacy. We now have a system of regulatory controls and enforcement that has established a floor for environmental protection.

In some cases, OSHA may be an exception, we may have reached a point of diminishing returns, in that each incremental improvement in human health- and environmental-risk reduction comes only with a large increase in control costs, or benefits of additional regulation may be slight because so much has already been invested in environmental risk reduction. In still other cases, the cost of risk reduction is aggravated by the rigidity of the underlying command-and-control regulatory system. Rule-makings and permitting processes become de facto design standards sanctioning the use of specific technologies for pollution control. There may not be adequate flexibility for tailoring remedies to reflect the circumstances of individual sources and locations, including the relative advantages that different companies might have in choosing risk-reduction options. For some, especially small businesses, there may be a preference for design standards because resources for research and innovation are limited.

For progress to continue, we must look beyond command-and-control regulatory programs. The call for alternatives to command-and-control regulations was particularly strong in presentations received by the Commission outside of Washington, D.C. In addition, federal agencies emphasized their commitment and cited their projects aimed at finding effective alternatives to command-and-control regulation. This subsection discusses several analytic tools for identifying when environmental protection is improved and risk reduced, and endorses a number of alternatives to command-and-control regulation that should be considered when there is interest in going beyond current levels of protection and risk reduction.

FINDING 5.4: Risks to human health and the environment have been reduced over the last 25 years primarily through command-and-control regulations of existing and new sources of emissions and testing requirements for newly developed chemical products. However, serious problems in the regulatory system have developed in some situations: delays in human-health and environmental protection, litigation, and compliance costs that are often out of balance with their benefits. Executive Order 12866 stresses the use of performance goals for environmental protection to increase the flexibility industry has to pursue the most effective and efficient solutions.

RECOMMENDATION: Regulatory agencies and affected communities should aggressively consider alternatives to command-and-control regulation using the Commission's risk-

management framework to improve the efficiency and effectiveness of protecting human health and the environment and to reduce compliance and litigation costs. A sense of experimentation and a commitment to evaluation are key elements.

RATIONALE

Government must set environmental protection standards, but there are important economic and environmental benefits in allowing companies and communities greater flexibility in determining how to meet those standards. Greater flexibility must be coupled with agency monitoring and enforcement, however, to ensure that the expected level of environmental protection is being achieved. In addition, the equity of who benefits and who pays the cost under alternative environmental-protection approaches should be compared with the equity of who benefits and who pays the cost under the status quo. Jonathan Howes, Secretary of the Noth Carolina Department of Environment, Health, and Natural Resource, in reporting to the Commission on the work of the National Academy of Public Administration, said they concluded that many businesses have found it in their interest to meet or exceed environmental standards, particularly if they can use their own strategies to achieve the pollution reduction targets that are established.

Environmental accounting, industrial ecology and life-cycle analysis, and environmental audits are emerging analytic tools that can assist in understanding the consequences of economic activity and environmental-protection efforts. Alternatives to command-and-control regulation that are being tested include market-based incentives, taxes and subsidies, right-to-know laws and other incentives to encourage pollution prevention, alternative compliance, and consensus, mediation and dialogue projects. Those tools are options to be used when and where they make sense in responding to additional risk reduction opportunites. As the alternatives are being tested, it is important to evaluate them for reliability in meeting or exceeding environmental goals, feasibility of implementation, and general effectiveness and efficiency.

Tools for Understanding the Consequences of Economic Activity and Environmental Protection

Environmental Accounting. There is a movement from traditional accounting systems toward "environmental accounting" for both national and business accounts. In June 1995, EPA published *An Introduction to Environmental Accounting as a Business Management Tool: Key Concepts and Terms;* many private-sector and private-public partnership forums are addressing this topic.

In traditional accounting of revenue, expenses, and net income of businesses, energy costs are lumped in overhead, and effects on and uses of resources—such as air, rivers, soils, and other environmental components—are neglected altogether. The challenge is to incorporate *all* costs involved in design, production, use, disposal, and reuse so as to arrive at a life-cycle analysis of a product or process. Assigning values to various environmental assets used and to real or potential environmental effects that have varied probabilitiesis problematic, however. Those assigned values may well drive the results of the analysis. Nevertheless, the process of

environmental accounting can link environmental costs with activities and products and provide information that results in win-win opportunities to increase operational efficiency, improve worker safety, enhance product quality, and meet environmental protection goals. Bankers and investment advisers have been slow to encourage up-front investments in those cost-saving initiatives. The President's Council on Sustainable Development (1996) recommended that national business associations provide technical assistance to companies interested in identifying environmental management costs and innovative ways to increase profits by reducing energy and materials use while better protecting public health and the environment.

Industrial Ecology and Life-Cycle Analysis. Proponents of industrial ecology envision a closed-loop system in which no resources are depleted; that is, all materials are perpetually reused, and no waste is produced or discarded. The loops might be closed within a factory, among industries in a region, and within national or global economies. Industrial ecology would integrate the producing and consuming segments of an economy to optimize the use and recycling of industrial materials and products. "Benign by design" chemistry, in which synthetic chemistry is designed to use and generate fewer hazardous substances, is a step toward achieving a closed-loop system. Quad Graphics, a Wisconsin based printing business, and Stonyfield Farm, a yogurt producer located in New Hampshire are trying to establish eco-industrial parks where companies with compatible production processes can use resources more efficiently and reduce waste. Life-cycle analysis is important to the implementation of industrial ecology, because it provides information that can be used to understand the consequences of choices among materials, product designs, and process designs and to understand the fate of products when they are finally discarded by consumers. Nevertheless, industry representatives emphasize that life-cycle analysis relies on many assumptions and needs further research and development before it can be a reliable tool.

Environmental Audits. Audits by industry and by third parties are a powerful tool for influencing corporate compliance with command-and-control regulations by easing penalties for self-disclosed violations. Audits also allow emitters to highlight voluntary reduction of pollutant emissions to the air, water, and land. Environmental audits have become controversial with the passage of recent state legislation providing blanket protection from penalties for self-disclosed violations.

Alternatives to Command-and-Control Regulation

Market-based Incentives. Market-based incentives rely on economic motivations to encourage environmental protection and cost effectiveness. A prominent example of market-based incentives to achieve environmental protection is the use of tradable sulfur dioxide emission allowances to reduce acid rain. This program, mandated under the 1990 Amendments to the Clean Air Act, permits electric utilities to reduce their emission of sulfur dioxide, the precursor to acid precipitation, below allowable levels and sell the unused emission allowances to companies whose cost of compliance is substantially greater. The program caps aggregate sulfur dioxide emissions well below historical levels while allowing emission reductions to be achieved more cost-effectively than by requiring every company to install the most-expensive

sulfur dioxide control technology. The cost of a ton of sulphur dioxide emission allowances has fallen below projected costs, presumably reflecting technological advances. Similar programs are being developed to reduce regional nitrogen oxide emissions. The use of caps and tradable pollution allowances may not work well in some cases such as toxic air pollutants where sources create localized risks.

Right-to-Know and Other Incentives to Encourage Pollution Prevention. In addition to the use of direct economic-incentive policies, other positive incentives are available to encourage pollution prevention, some of which EPA has implemented. For example, some pesticides that require approval by EPA before they can be distributed, used, or sold could be given priority for approval if they were deemed safer for human health and the environment, and thereby reach the marketplace faster than other pesticides. If regulations control the labeling of a product, safer products could receive more favorable treatment, such as authority to use a special label, to give them greater prominence in the market. To encourage pollution prevention by manufacturing facilities, businesses might be given tax incentives to replace old facilities with new, cleaner processes that do not generate waste and pollution. Another example pertaining to Title V permits under the Clean Air Act is EPA's Pollution Prevention in Permitting Pilot Project (P4 Project) with Intel Corporation, the Oregon Department of Environmental Quality and the Northwest Pollution Prevention Research Center. The pilot is now being extended to five other companies in EPA regions 1, 4, 6, 9, and 10. The aim is to reduce production of air emissions, rather than control their release in ways that generate solid waste or waste water.

The Toxic Release Inventory and California Proposition 65 have proved effective pollution prevention incentives by requiring the disclosure of information about chemical releases to the environment and labeling of chemicals in products, respectively. Those right-to-know laws rely on the public's attitudes toward toxicants to encourage industry to reduce or eliminate their use or release. In the case of Proposition 65, the requirement to warn people about exposures to chemicals known to cause cancer, birth defects, or other reproductive harm has been an incentive to businesses to eliminate such chemicals or reduce exposures and associated risks below the bright lines for cancer and reproductinve risks. Rather than relying on command and control, Proposition 65 uses disclosure of information and labeling requirements as risk-management tools. Proposition 65 places the burden of proof of safety on manufacturers rather than on government agencies, requiring businesses to present a risk-based analysis to avoid having to label their products and substances as cancer-causing or reproductive toxicants. David Roe of the Environmental Defense Fund informed the Commission that Proposition 65, once enacted and implemented, has had widespread support from environmental and business communities and has had few legal challenges. A key element was the decision by the state agency, accepted by environmentalists and business, to put the bright line for cancer risk at 10^{-5}, rather than 10^{-4} or 10^{-6}, as proposed by contending parties. He estimated that under this system, the state of California completed the necessary regulatory work for 282 chemicals at a cost of about one-tenth of what EPA was spending on risk assessment during the same years.

Taxes and Subsidies. Tax and subsidy programs that encourage and discourage economic activity can be powerful motivators, either encouraging or discouraging use of natural resources

and production or reduction of pollution. For example, agricultural land-retirement programs have prevented excessive soil erosion and damage to waterbodies and wildlife habitat, and promoting agricultural production through implicit and explicit subsidies for inputs, such as pesticide and water use, can contribute to environmental damage. Elimination or amelioration of negative-tax and subsidy programs can have a positive impact on the protection of human health and the environment, as can carefully targeted increases in subsidies for the provision of some environmental benefits. Government purchasing practices can also encourage the development of markets for products that are environmentally more sound. Care is needed to avoid excessive acquisition costs for products with small markets and to avoid buying products with one attractive attribure but other unfavorable characteristics.

Alternative Compliance. Alternative compliance provides greater flexibility to industry by allowing choices of methods for achieving emission-reduction or risk-reduction specifications. It is designed to achieve higher levels of environmental protection at lower cost and to foster integration of local concerns in environmental risk-management decisions. Alternative compliance gives regulated entities the ability to choose among a broad range of management alternatives instead of being subject to prescriptive command-and-control requirements. This option can result in substantial savings for industry, communities, or any regulated entity that participates. For example, EPA's Project XL allows six companies (Intel Corporation, Anheuser Busch Companies, HADCO Corporation, Merck & Co., Inc, AT&T Microelectronics, and 3M Corporation) and two government agencies (California's South Coast Air Quality Management District and the Minnesota Pollution Control Agency) to experiment with different strategies for improving environmental protection. Government also can provide greater compliance flexibility for those attempting to use innovative pollution-reduction and-control technologies. Use of the concept of a bubble to encompass a facility or geographic area and seek the best way to reduce a pollutant or pollutants within the bubble has provided flexibility in compliance, also.

Consensus, Mediation, and Dialogue Projects. Negotiated rule-making and dialogue projects, such as EPA's Common Sense Initiative, offer opportunities for stakeholders to design new standards and solutions that protect human health and the environment more reliably and with greater cost effectiveness and public acceptance. With the Common Sense Initiative, begun in 1994, EPA has convened consensus-oriented teams of stakeholders to look for opportunities to turn complicated and inconsistent environmental regulations for six major industries—automobile manufacturing, computers and electronics, iron and steel, metal finishing, petroleum refining, and printing—into comprehensive sector-specific strategies for environmental protection. Several industrial sectors have launched their own intitiativces such as Responsible Care by the Chemical Manufacturers Association.

The Commission joins with the President's Council on Sustainable Development (1996) in endorsing alternatives to command-and-control regulations. Wise use of a variety of alternatives might provide increased human-health and environmental protection with greater efficiency and lower cost to regulatory agencies, industry, the economy, and society, than command-and-control programs.

5.5

Peer Review

The importance of peer review in regulatory decision-making has been highlighted recently by the prominence of requirements for peer review in several regulatory-reform bills before Congress. Earlier versions of those bills included prescriptive instructions regarding the nature and duties of peer-review panels. Later versions of the bills have been less prescriptive. Peer review is an important and effective mechanism for evaluating the accuracy or validity of technical data, observations, and interpretations, and the scientific and economic aspects of policy recommendations and regulatory decisions.

FINDING 5.5: Peer-review activities in federal regulatory agencies are generally devoted to evaluating the quality of the science and the scientific interpretations that underlie a regulatory decision. The quality and interpretation of other technical information, especially that related to economic analysis and the social sciences, are generally ignored. Peer review has not been used to evaluate the use of scientific and economic information in regulatory decisions, however, and there are no procedures for evaluating the effectiveness of peer review itself. Several agencies do not have official guidelines or policies for peer review. Of course, peer review can be overdone; implementing a peer-review process for every regulatory decision or every step in a regulatory decision would lead to substantial delay and require excessive resources.

RECOMMENDATION: The role of peer review should be expanded to consider not only the quality of technical information, but the use of that information in regulatory decision-making. Peer review of economic and social science information should have as high a priority as peer review of health, ecologic, and engineering information. Clear, written guidelines for peer review should be established by regulatory agencies, and the effectiveness of agency peer-review programs should be evaluated regularly. The level of peer review should be commensurate with the level of scientific or economic importance and regulatory impact of the decision to be made. Peer review should be conducted not simply to seek legitimacy for agency decisions and positions, but to improve their quality. When peer review is judged to be unnecessary, an agency should provide an explanation and justification.

RATIONALE

Peer review provides independent views of an issue. When used well, peer review can serve as a system of checks and balances for the regulatory process. In the context of risk analysis, an open process for peer review can increase the credibility of and confidence in an assessment. Peer review can make important contributions to a collaborative decision-making process that involves stakeholders. Administrative details—such as how peer reviewers are

selected, which agency products, regulatory options, or decisions will be subject to peer review, whether and how consistency among an agency's programs should be improved, and how the outcomes of peer review will be used—should be addressed by an agency's peer-review policies. EPA's program-specific standard operating procedures for peer review called for by its peer-review policy (EPA 1994) are examples of useful guidelines for peer review. Peer review of the output of the risk-assessment and options stages in the Commission's risk-management framework (section 2) is essential for all major rules under development. In some cases, peer review might be useful in the problem-formulation stage.

Good science can be used to justify bad regulations. Asking whether relevant scientific or economic information was cited appropriately in a particular regulatory process is critical. There appear to be no mechanisms in place that support peer review of the use of technical information at the policy stage. Perhaps scientific advisers to the EPA administrator, the FDA commissioner, or the OSHA administrator fill that role informally. Most peer reviews evaluate highly focused, technical topics because of the assumption that scientists and economists tend to lack an understanding of the history and philosophy of an agency's decision-making process. A mechanism for evaluating the descriptions and uses of scientific and economic analysis in the decision-making stage should be sought. The Commission does not suggest that the regulatory decision itself should be peer-reviewed, which, of course, is the purview of the judiciary.

Agency peer-review policies should include a regular evaluation process in which specific examples of an agency's use of peer review in its regulatory decision-making are examined. That evaluation would ask questions about how a peer review was conducted, whether and how the outcome of a peer review was used in a regulatory decision, whether the peer review was considered useful, and finally, how the process could be improved. A good example of agencywide evaluations of the role of peer review is described in the EPA publication *Safeguarding the Future: Credible Science, Credible Decisions* (EPA 1992b). Evaluations could be organized by the agency, such as EPA through its Science Advisory Board, or across agencies, such as by the Office of Science and Technology Policy or the risk-assessment subcommittee of the administration's Committee on Environment and Natural Resources.

Potential peer reviewers with clear conflicts of financial interest should be disqualified from service on peer-review panels that could directly influence regulatory decisions related to the products or interests of their organizations. However, it is difficult, if not impossible and unwise, to eliminate bias, which reflects views or positions taken that are largely intellectually motivated or that arise from a person's close identification or association with a particular point of view or with the position or perspectives of a particular group. The Commission believes that expertise, balance of biases, and inclusion of active, younger, and culturally diverse scientists, economists, and social scientists should be among the criteria for constitution of peer review panels. Explicit criteria for revealing and evaluating conflicts and biases are needed.

The person(s) responsible for selecting peer reviewers can have a great deal of influence on the

nature and biases of the membership, the expertise represented, and, by extension, the outcome of the review. Those persons can also have a lot of influence on what is peer reviewed. That gatekeeper role should be structured carefully to ensure that a small number of people do not have undue influence on reviewers' characteristics or decisions or on what is chosen for peer review.

Full peer review is unlikely to be needed for every regulatory decision. The most-effective and most-efficient use of peer review should be made case by case, taking into account such issues as the extent to which the scientific information on which a decision is to be based might be considered controversial, the economic impact that a decision might have, and agency resource constraints. Peer review should *not* be used as a device to delay controversial policy decisions.

5.6

Judicial Review

Introduction

Issues of judicial review that were raised by the 104th Congress—in the context of what was termed "regulatory reform" legislation and amendments to Administrative Procedure Act (APA)—were carefully analyzed, vigorously debated, and are likely to be revisited by Congress. Those issues focused debate on the proper role of judicial review of agency action in the regulatory process.

Conceptually, judicial review is the check by the judicial branch on agency activity at an appropriate stage of the administrative process, and in an appropriate manner and degree. Agencies are authorized to act and promulgate regulations under enabling statutes passed by Congress. The various enabling statutes also grant the right of, and limit the extent of, review of agency action by courts. Both agency action and judicial review of regulatory rule-making are governed by the provisions of the APA. A party that is affected by agency action can seek judicial review of that action in court when all other administrative remedies and appeals have been exhausted. However, a preliminary, procedural, or intermediate action by an agency that is not directly reviewable by a court is subject to review under the APA only upon final agency action, so that it will not interrupt the regulatory process prematurely.

A reviewing court adjudicates procedural issues, interpretations of constitutional and statutory provisions, and determinations of the meaning or applicability of the terms of agency action. It can compel agency action and hold such action to be unlawful if the court finds it to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, or in observance of procedure required by law. Moreover, when a reviewing court considers the record developed through formal agency hearings (formal hearings are required under certain enabling statutes), or when "substantial evidence" is otherwise required by statute, the court can hold agency action unlawful if that action is not supported by substantial evidence.

The Commission carefully considered the issues raised by proposed legislation and the effect of each of the regulatory rule-making process. In short, and as discussed below, the Commission submits that legislative initiatives should not provide for premature interruption of the administrative process, should not expand the nature and extent of judicial review in ways that will require courts to devote substantial time and resources to the oversight of agency compliance with detailed procedural requirements or the resolution of complex scientific issues, and should consider the use of alternatives that assure rational and cost-effective regulatory action.

Premature Interruption of the Administrative Process

FINDING 5.6.1: Interlocutory, or intermediate, appeals of discrete issues prematurely interrupt the administrative process.

RECOMMENDATION: Final agency action must, in fact, be final. Judicial review should be available only after agency action is complete and all administrative remedies have been exhausted. Amendments to the Administrative Procedure Act should not contemplate the premature interruption of the agency decision-making or rule-making process.

RATIONALE

Historically, provisions for judicial review under the APA grant review of the rule-making record for "final agency action". This practice limits parties from interrupting the administrative process by seeking judicial review of discrete issues until all other administrative remedies have been pursued and exhausted. The APA provides a procedural safeguard that not only ensures the establishment of a rule-making record, but preserves that record. Thus, in the administrative context, an agency has the opportunity to apply its expertise, exercise its informed discretion, and create a more complete record, so that if judicial review is invoked, there is a full record upon which a court can adjudicate.

Administrative procedure and practice require a party to challenge issues within the internal agency deliberative process. Issues raised in an administrative proceeding allow an agency to monitor and correct its mistakes, omissions, or oversights. Without resorting to costly lawsuits and court-imposed remedies, the administrative review process provides agencies with an opportunity to research and develop more fully a record that identifies issues considered as part of the rulemaking process.

Proponents of some legislative initiatives maintained that they preserved the APA's premise that only final agency action is reviewable, but there were suggestions and debate as to what was considered to be final agency action. In various drafts of proposed legislation, a number of initial and intermediate agency determinations in the rule-making process were deemed final agency action. That would have created an opportunity to leap immediately—and prematurely—out of the administrative context, where issues could be developed fully, and into the judicial arena, under the guise of final agency action. Considering this scenario in the context of drafting and implementing agency regulations, interested parties could prematurely, and in piece-meal fashion, seek judicial review of discrete issues and effectively delay and hamstring the regulatory process.

Allowing premature interruption of the administrative process limits—if not impedes—the rule-making record. As a consequence, judicial review would proceed on an incomplete record and issues would be adjudicated without a full and fair development of the underlying data and benefit of scientific analysis.

Interlocutory review is inconsistent with notions of litigation reform, which were also major goals of the 104th Congress.[1] In addition, new opportunities for judicial review would result in costly and unacceptable delays in the rule-making process. Simply stated, interlocutory appeals of agency actions are not supported historically and limit the development of regulatory initiatives by prematurely interrupting the regulatory rule-making process.

* * *

The nature and extent of judicial review

FINDING 5.6.2: Recent proposed legislation included detailed requirements governing the content of risk assessments and cost-benefit analyses, the procedures for preparing the analyses, and the regulatory decisions based on the analyses. Under accepted administrative law requirements, all those new requirements would be judicially reviewable, potentially leading to increased and more complex litigation over agency decision-making on highly scientific substantive matters.

RECOMMENDATION: Provisions that would make substantive risk assessments and cost-benefit analyses and their underlying factual support subject to expanded judicial review, as well as prescriptive and detailed procedures for conducting those assessments and analyses, should not be legislatively grafted onto existing enabling statutes. Instead, a legislative program-by-program approach would assure that such requirements fit the statutory scheme and would help tailor such requirements to that scheme, thereby reducing the potential for unnecessary litigation. Court review should remain confined to questions of law, constitutional and procedural issues, and whether the agency's finding, determination, or decision was arbitrary or capricious under the traditional deferential standard (unless the enabling legislation otherwise provides). Following that standard, courts should continue to defer to agency expertise and peer review in areas involving highly scientific analysis.

RATIONALE

Courts are the appropriate reviewers of statutory and regulatory limitations of rights and obligations, of broad process and procedural rights and, of course, of legal issues and the interpretation and application of precedent. In general, courts are not best equipped to assess in detail and delve deeply into the technical science that supports much agency decision-making. Although all issues of scientific method and factual support for findings are currently subject to judicial review, courts instead typically have undertaken broad oversight of agency scientific findings under the "arbitrary and capricious" standard of review. This standard is deferential to agency scientific decision-making and allows agencies substantial flexibility in drawing upon their specialized expertise, while ensuring judicial oversight to ensure that administrative agencies follow accepted procedures and standards and do not, broadly

[1]Congress overrode a presidential veto to enact securities-reform legislation and also seriously considered and debated tort reform to decrease the amount of litigation.

speaking, act in an improper manner (i.e., arbitrarily or capriciously). Indeed, one of the primary reasons administrative agencies were created in the first place was to bring specialized expertise to bear on complex issues.

Some proposed legislative initiatives would change the nature and extent of judicial review of agency decisions in a number of ways. A legislative mandate to agencies to follow intricate, detailed procedures in developing cost-benefit analyses and risk assessments, combined with a change in the standard of judicial review of agency decision-making from the "arbitrary and capricious" standard to the less deferential "substantial evidence" standard (discussed in more detail in section 5.6.3), inevitably would involve courts in an investigation of much more than whether a "rational basis" exists to support an agency rule. In addition to examining agency compliance with detailed substantive and procedural requirements contained in the legislative proposals under a broadened "substantial evidence" standard, courts would likely be required to delve far more deeply into the many complex scientific issues affecting a rule. That would create not only increased opportunities for litigation, but much more complicated and expensive litigation. The end result may well be that courts, without any significant scientific expertise in the subjects being adjudicated, would replace administrative agencies as the ultimate decision-maker on many highly technical, specialized issues.[2]

In addition to requiring risk assessments and cost-benefit analyses, some proposed legislation would establish criteria ("decisional criteria") that would be used to evaluate the validity of a rule, and would supplement all enabling statutes. Consequently, the findings of cost and risk evaluations, conflicts with regard to scientific data, the postulates representing the most reasonable inferences from supporting toxicologic and epidemiologic data, and determinations of whether an agency sufficiently used the appropriate information in its analysis, would become inexorably part of the agency record and, therefore, the subject of judicial scrutiny. Some statutes administered by federal agencies now preclude reliance upon benefit-cost analyses or risk assessments in regulatory decision-making. For example, when EPA sets national ambient air quality standards (NAAQS) under section 109 of the Clean Air Act, it must rely on technology and cost considerations, and not the results of risk assessments (section 112 provides for risks to be considered at a second, later regulatory phase). Because many of the legislative proposals would overlay these laws with new requirements that decisions be based on benefit-cost analyses and risk assessments, they would greatly expand the number of issues that the Agency would have to analyze and that could be presented, in turn, to courts. Rather, we suggest the policy of including risks, costs, and benefits as decision criteria be established and pursued on a legislative program-by-program basis to ensure that the administrative rule-making process does not itself increase in complexity and duration, consuming more agency resources and time to complete individual rule-makings.

We recommend that courts should focus on that for which they are best equipped—reviewing agency compliance with the broad procedural requirements that currently govern agency

[2]Unless the enabling legislation otherwise provides.

action and reviewing whether an agency decision is arbitrary and capricious in light of the goals of the underlying statute.

* * *

Standard for Judicial Review

FINDING 5.6.3: Enhanced standards for judicial review would reverse years of precedent and expand the historical role of the courts in reviewing agency action.

RECOMMENDATION: The standards by which courts review agency regulatory action, exercising great deference to agency interpretations of highly technical and scientific areas, should not be expanded.

RATIONALE

Historically, the standard by which courts have reviewed most agency regulatory action has been the narrow "arbitrary and capricious" standard. Under the arbitrary and capricious standard, courts consistently have held that agencies are entitled to great deference with regard to factual questions involving scientific matters in their own fields of expertise. Such deference has extended to mixed questions of law and fact, at least to the extent they have been fact-dominated. For example, in the case of *Northwest Motorcycle Association v. United States Department of Agriculture*,[3] an off-road vehicle (ORV) association petitioned for review of the United States Forest Service's decision to close forest trails to ORVs in designated areas of the Wenatchee National Forest. After exhausting all administrative remedies, the ORV association argued before the United States Court of Appeals for the Ninth Circuit that the Forest Service's conclusion was arbitrary and capricious.

In holding that the decision to close the trails was not arbitrary and capricious, the circuit court limited its review to the administrative record as required under the provisions of the APA.[4] The court recited "evidence in the administrative record" that supported the Forest Service's findings, and cautioned that "the court here is reviewing the evidence only to determine whether such evidence existed that justified the [Forest Service's] decision."[5]

The ORV association pointed to a number of alleged deficiencies in the administrative record. The court, however, replied that these deficiencies did not "mandate a finding that the [Forest

[3]18 F.3d 1468 (9thCir. 1994).

[4]Pursuant to 5 U.S.C. §706 of the APA, final agency action is reviewable; however, review is limited to the administrative record.

[5]See 18 F.3d at 1473, fn 2.

Service's] decision was arbitrary and capricious."[6] Rather, the court opined that the Forest Service, as fact-finder, was in the best position to determine the credibility of the evidence.[7] Acknowledging the long-standing precedents of judicial review under the APA, the court noted that it "is not empowered by [the APA] to substitute its judgment for [the] agency."[8] Thus, the basic standard for review of informal regulatory rulemaking is whether the agency action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." The scope of review under this standard is a narrow one. In *Citizens to Preserve Overton Park v. Volpe*,[9] the United States Supreme Court held that agency action is entitled to a "presumption of regularity" and while that does not "shield [it] from a thorough, probing, in-depth review," the "ultimate standard of review is a narrow one." The reviewing court is to search for a "clear error of judgment," and cannot "substitute judgment for that of the agency."[10]

A starting point for analysis of the proper standard of review is an explanation of the type of findings and type of file that are typical to informal rule-making. The findings and file reviewed under the arbitrary and capricious standard differ substantially from those required in formal adjudications under the APA.[11] The agency is not required to supply specific and detailed findings and conclusions, but need only "incorporate in the rules a concise general statement of their basis and purpose." The agency need not discuss every item of fact or opinion included in the written comments submitted to it, although it must respond to those comments and not be arbitrary and capricious. The "basis and purpose" statement must identify "what major issues of policy were ventilated by the informal proceedings and why the agency reacted to them as it did." In addition, the record "ordinarily will contain more generalized than specific information, may not contain information tested by cross-examination and will frequently contain much more conclusory information based on data gathered by interested parties."[12]

The court's paramount inquiry is whether a reasoned conclusion from the record as a whole could support and explain the agency's course of action.[13]

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[6] *Id*. at 1476.

[7] *Id*. at 1476.

[8] *Id*. at 1476.

[9] 401 U.S. 402, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971)

[10] See *Citizens to Preserve Overton Park*, 401 U.S. at 415-16, 91 S.Ct. at 823-824.

[11] Formal agency adjudications, on appeal, are reviewed under the substantial evidence standard.

[12] *Id*., at 1204.

[13] See *Citizens to Preserve Overton Park*, 401 U.S. 402, 91 S.Ct. 814; *American Medical Association v. Matthews*, 429 F.Supp. 1179 (N.D. Ill 1977).

Proposed legislation appeared to greatly expand the use of the broad substantial evidence standard now reserved for formal agency adjudications, at the expense of the more narrow arbitrary and capricious standard. Proposed amendments to the APA would compel courts to hold agency action unlawful if the agency findings and conclusions are found to be "without substantial *support* in the rulemaking *file*, viewed as a whole, *for the asserted or necessary factual basis . . .*" [emphasis added]. Thus, the substantial evidence standard apparently would be expanded beyond formal hearings to all rulemakings.

While the substantial evidence standard is not a new standard of review, it typically (although not exclusively; see, for example, TSCA) has been reserved for formal rule-making and hearings. Courts have expressed some question about the application of the substantial evidence standard to informal rule-makings where the evidentiary standards and record development are different than in formal hearings (see, for example, *Aqua Slide 'n' Dive v. CPSC*[14]). Courts that have historically deferred to agency interpretation and action under an arbitrary and capricious standard[15] would, instead, have to find substantial support for that action in the agency file. Inherently, requiring a court to find substantial evidence lessens its ability to defer to agency decisions.

The Commission submits that years of judicial and administrative precedent are well founded. Agencies, not courts, are better equipped to analyze highly scientific and technical findings. That precedent should not be legislatively overruled by expanding the standard of review.

* * *

Impact of increased litigation on agencies, parties, and the courts

FINDING 5.6.4: Our court system is backlogged and agencies are heavily burdened. Each is often incapable of handling its caseloads. Consequences of increased judicial review through interlocutory appeals and an expanded scope and standard for review could include a new wave of litigation causing more delay and more costs to agencies and parties, without producing improvements in the quality of the decisions or benefits to the parties involved.

RECOMMENDATION: Initiatives that are likely to increase litigation and the role of the courts should not be undertaken.

RATIONALE

[14]569 F.2d 831 (5th Cir. 1978)

[15]Obviously, we are not addressing those specific statutes that individually require a substantial evidence standard. Nor are we suggesting that in future legislative initiatives Congress does not have the prerogative to require the substantial evidence standard. Rather, we are addressing a wholesale approach supplementing all existing legislation.

As already noted, expanded judicial review under the proposed legislation would represent an historic retreat from precedential notions of judicial deference and restraint. The APA provides procedural avenues that are aimed at preventing arbitrary or capricious action by an agency. Moreover, under the APA, judicial intervention is called for, appropriately, at the end of the administrative process, when the record is full, developed, and complete, not near the beginning or in the middle of that process. The wave of science- and medicine-based litigation involving, among other things, asbestos and lead-based paint, that flooded the courts in the 1980s and early 1990s provides meaningful examples of how questions of science can open up a universe of litigation that results in massive delay and massive costs, without necessarily producing improvements in the quality of decisions or benefits to the parties involved.

We are not suggesting that courts steer away from science issues when considering those questions in the regulatory context. The question is not whether but to what degree a court reviews science-based regulatory decision-making. Increasing judicial involvement as described above act only to delay, burden, and increase costs to agencies and parties.

Alternatives to increased judicial review

FINDING 5.6.5: Consensual approaches to decision-making that would help assure rational and cost-effective regulatory actions affecting health, safety, and the environment as alternatives to increased judicial review are not commonly used.

RECOMMENDATION: Regulatory agencies should maximize consensual approaches to decision-making such as negotiated rule-making, alternative dispute-resolution techniques, expert peer review, and informal practices such as meetings with groups of representatives of interested parties, involvement of community stakeholders, and workshops to explore alternative regulatory approaches. Congress, in turn, should explore with the agencies removal of possible obstacles to these practices that may exist under current law.

RATIONALE

Alternatives to judicial review that promote dialogue, interplay, and negotiation between regulators and the regulated community are not commonly used, other than in the context of agency policy initiatives. While variations of alternative dispute resolution (ADR) procedures are sometimes used in the rulemaking and enforcement arenas, they clearly are the exception and not the rule.

For example, members of the regulated community, public-interest groups, and other interested parties engaged in a negotiated rule-making process work together to analyze and discuss proposed regulatory initiatives. Those negotiated rule-making sessions allow the promulgating agency to understand fully and develop possible alternatives to a regulatory initiative. The development of achievable standards or alternatives to regulatory controls are contemplated, tested, and implemented, and regulatory goals are achieved rather than violated.

EPA has embraced this concept with its Common Sense Initiatives, and for those stakeholders involved, the process has opened up communications with the regulatory agency. In turn, fewer legal challenges are filed in the course of the rule-making process.

In some instances, current laws may stand as obstacles to consensual approaches in regulation. For example, the Federal Advisory Committee Act prohibits federal agencies from organizing groups of interested but unrelated parties to seek consensus, unless the groups are chartered by the Office of Management and Budget (OMB) as advisory committees and detailed procedures, including notice of meetings in the Federal Register, are followed. As a result, agencies are faced with either resorting to the inefficient practice of meeting one by one with affected groups, or accepting the substantial delays associated with chartering advisory committees.

Similarly, agencies that seek to gather information on a voluntary basis from the regulated community or others are often prohibited by the Paperwork Reduction Act from doing so—even on a voluntary basis—unless they seek and obtain clearance from OMB. Other statutes that require publication and formal notice of meetings, such as the Government in the Sunshine Act, may unintentionally chill efforts by agencies such as the Federal Energy Regulatory Commission and the Consumer Product Safety Commission to use informal consensus-building approaches.

Congress might explore with affected federal agencies whether it would be useful to relax some of these restrictions to make consensus-building approaches more readily available. Agencies such as EPA have demonstrated their readiness to use these techniques and the law should not restrict their use unnecessarily.

6

Recommendations for Specific Regulatory Agencies and Programs

Current practices in the use of risk assessment in regulatory programs vary among Federal agencies and even among regulatory programs within the Environmental Protection Agency (EPA). Some of the variation is attributable to different requirements among federal laws authorizing regulatory activity, either in the form of explicit methodologic requirements that assessments must follow or as differently mandated regulatory responsibilities that the assessments must support. And some of the variation reflects differences in policy among organizations, adopted as a matter of differing scientific and policy judgment or simply because of the independent establishment of varied precedents and preferences. Better coordination among agencies is needed, and there have been several calls for a central organization to coordinate all risk-assessment activities.

Previous sections of this report have addressed the larger risk-assessment and risk-management issues that affect environmental, health, and safety regulatory programs across the federal government. This section narrows those general issues and recommendations to individual agencies and programs and uses them as a basis for specific recommendations. This section is not meant to be an exhaustive evaluation of all the federal agencies that assess and manage risks, but to highlight those that provided testimony to the Commission.

FINDING 6.1: Risk-assessment practices are poorly coordinated among and often within regulatory agencies and programs, even among those with overlapping interests and jurisdictions. Inconsistencies and idiosyncratic practices impair the credibility of risk assessment.

RECOMMENDATION: When two or more agencies or program offices regulate similar health or ecological hazards associated with chronic exposures, they should coordinate their risk-assessment methods and assumptions, unless there is a specific statutory requirement for different choices or a scientific disagreement, which should be explicated.

RATIONALE

The primary reason for differences among agencies in performing risk assessments is that the function of the risk-assessment process—to project possible human health risks associated with the various types and magnitudes of exposures that might arise—outstrips the ability of scientific investigation to give firm answers. The practical need remains to characterize the risk consequences (including the uncertainty about them) of various potential actions and activities by industries, by government, by individuals, and by society as a whole.

There is general agreement on a common framework and structure for risk assessment, but debate continues vigorously about the most-appropriate risk-assessment approaches, the bearing of various kinds of data on risk projections, the level of risk that is considered negligible, and the degree and appropriateness of conservatism in risk-assessment methods. The effect of the diversity of methods among federal regulatory agencies is to make it difficult to compare risks, or the actions taken to mitigate those risks, from one regulatory program to another. For example, EPA and the Consumer Product Safety Commission (CPSC) differ on several critical aspects in the performance of a quantitative risk assessment, including reliance on the "maximally exposed individual" or other upper-end exposure estimates at EPA versus the average population exposure at CPSC and the use of upper-bound risk estimates at EPA versus maximal-likelihood estimates at CPSC. EPA occasionally uses pharmacokinetic information for cross-species extrapolation, but CPSC has declined to do so.

Although defaults and standard methods are necessary in the face of uncertainty and lack of case-specific knowledge, variation among agencies and programs increases the sense of arbitrariness in risk analyses. In cases where regulatory responsibilities overlap or different groups have cause to assess the same exposures, differences in assessment outcome can lead to conflict and confusion among the public and the regulated community. When inconsistencies exist among agencies with overlapping regulatory responsibilities, a continuing effort is needed to harmonize methods and assumptions used in risk assessment. In cases where consistency is inappropriate, written justification should be provided. Lorenz Rhomberg's report to the Commission details the use of risk assessment by federal agencies and indicates where some of the inconsistencies exist (see appendix A.6).

6.1

Environmental Protection Agency

EPA has played a critical role in facilitating the substantial improvements in our environment that we have enjoyed over the last 25 years. The major sources of pollution contaminating our air, water, and soil have been greatly mitigated, largely as a result of its efforts. The complex and intransigent problems that remain will require continued creativity and, in some cases, improved efficiency. This section addresses several of EPA's programs and offers recommendations that are aimed at improving the identification and management of risks.

6.1.1

Office of Air and Radiation

The Clean Air Act Amendments of 1990 contain several provisions of particular relevance to the Commission concerning the assessment and control of criteria air pollutants (section 109) and hazardous air pollutants (section 112). The same sources often contribute pollutants of both types. For example, motor vehicles are major contributors of the criteria air pollutants ozone, carbon monoxide, and particles, and they are also the source of about one-third of all hazardous air pollutants, including benzene, 1,3-butadiene, and formaldehyde. Similarly, point sources, especially those which use large quantities of volatile organic compounds, contribute to both the regional ozone air-pollution problem and increased concentrations of hazardous air pollutants in the local environment.

The 1990 amendments to section 112 established an entirely new program to control hazardous air pollutants from point sources through the promulgation and implementation of technology-based standards embodied in what is known as maximum available control technology (MACT). Congress required that the need for further control be determined through risk-based approaches after implementation of MACT. The MACT strategy was mandated because the regulation of hazardous air pollution from point sources with a purely risk-based approach seemed to be ineffective and inefficient. Difficulty in setting new standards was attributed to “paralysis by analysis”, according to the National Resources Defense Council’s David Hawkins, who was assistant administrator for the Office of Air and Radiation under President Carter. Although most air pollution had been regulated, there had been relatively little impact on the tonnage of pollutants released into the air, as was evident from Toxic Release Inventory data. It is not known whether a technology-based approach will be more effective in protecting public health than a risk-based approach.

As of May 1996, EPA had promulgated 27 MACT standards (including 10 in the overall category of hazardous volatile organic chemicals) and had proposed four more; a total of 174 source categories need one or more MACTs each. Full MACT implementation is projected by EPA to cost about $600 million per year and to reduce hazardous air-pollutant emissions by 880,000 tons and criteria air-pollutant emissions by 1,900,000 tons per year.

The risks that will remain after MACT standards are in place (residual risks) have not yet been determined. Preliminary analyses are being conducted at EPA. The agency is applying a case-study approach to assess data availability and to evaluate screening methods and models that might be used in the residual-risk program. Criteria that will be used to choose screens include ease of use (so that “nonexperts” can conduct screening assessments) and extent of conservatism. The goal is to find a method or methods that will eliminate from further analysis sources that are clearly of no concern and focus attention on sources that need

further, more-rigorous analysis. One potential screening method is EPA's three-tiered analysis described in appendix J of *Science and Judgment in Risk Assessment* (EPA 1992d, NRC 1994a). Tier 1 is a conservative screen that requires only stack heights, distances to fence lines, emission rates, and "lookup tables" to obtain maximal off-site concentrations. Tier 2 is also conservative, adding to tier 1 data only some generalizations about stack characteristics and a distinction between urban and rural environments. EPA's preliminary evaluations using the tiered approach demonstrate the enormous data gap that must be filled even to perform screening analyses, much less estimate residual risks reliably; there were enough data to evaluate only seven source categories at tier 1 and for only two of those were there enough data to proceed to tier 2.

This section presents recommendations regarding the assessment of residual risks after MACT, as the Commission was mandated to do by Congress, and addresses several other MACT-related issues. We also address the topic of indoor air pollution.

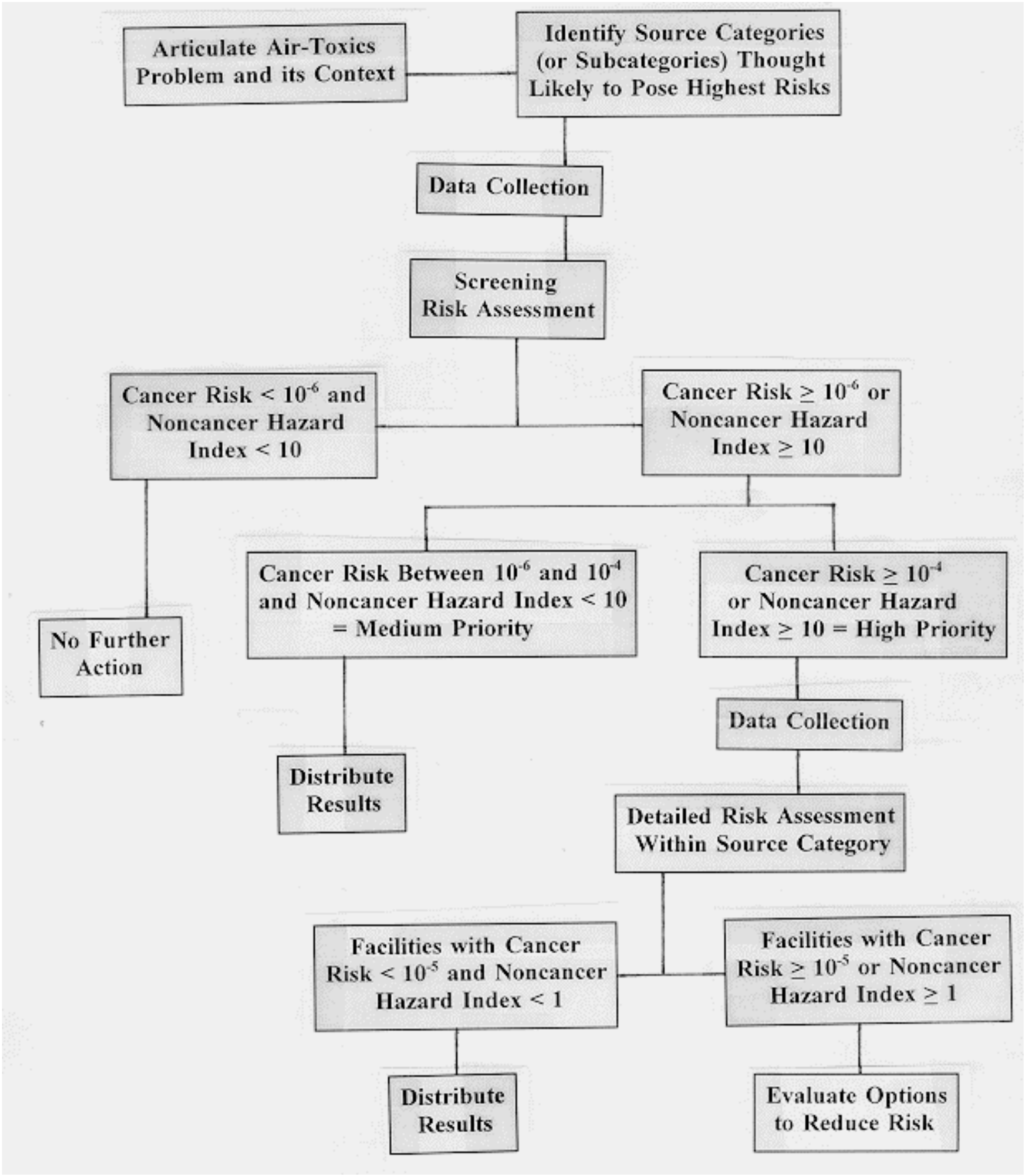
FINDING 6.1.1.1: EPA needs and wants guidance on how to implement the residual-risk provisions of the 1990 amendments to the Clean Air Act after controls have been put in place to meet technology-based standards. The current Clean Air Act requirements can be interpreted to imply that if even a single facility within a source category is found to pose a residual cancer risk of 10^{-6} or more after maximum available control technology (MACT) has been implemented, EPA must set new standards for the source category. That policy could lead to devoting extensive resources to pollution controls where there are no important risks.

RECOMMENDATION: To determine and manage residual risk after implementation of MACT, the Commission proposes a specific tiered scheme (see figure 6.1): characterize and articulate the scope of the national, regional, and local air-toxics problems and their public-health and environmental contexts; obtain necessary data and perform screening-level risk assessments to identify sources with the highest risks; conduct more detailed risk assessments of sources and facilities with the highest risks; evaluate risk-reduction options at facilities that have incremental lifetime upper-bound cancer risks greater than one in 100,000 persons exposed or, for noncancer risks, concentrations greater than reference standards, using the Commission's risk-management framework set forth in section 2; and determine the need to evaluate residual risks from less high-risk source categories. The scheme is described in detail below.

1. Problem/Context Characterization. To provide guidance for stakeholders and for implementing the residual risk-assessment and risk-management scheme, the scope of the local, regional, and national air-toxics and air-pollution problems are characterized. The problems are put in context by comparing air-toxics issues to air-pollution issues in general and to other, multimedia sources of exposure to the same chemicals. The goal is to build an understanding among stakeholders about the health context of residual risks from regulated point sources of emissions.

2. Screening Risk Assessments. Priority source categories or subcategories are identified that

Figure 6.1. Scheme for determining and managing residual risk after MACT.



the agency considers likely to pose the highest residual risks. Screening risk assessments of facilities are performed by source category (or subcategory), starting with those which the agency has identified. Screening risk assessments can follow methods such as EPA's tier 1 or tier 2 procedures for assessing risks from hazardous air pollutants (EPA 1992d, NRC 1994a). Screening risk assessments must rely on many default assumptions and the defaults must be realistic and chosen with care. The specific methods, criteria, and assumptions for performing screening risk assessments should be developed by EPA in partnership with state environmental regulatory agencies, with appropriate peer review and stakeholder input in an open and transparent process.

Successful implementation of screening risk assessments will require more and better data than are now available to EPA. EPA should establish a miminal data-quality requirement for source-category emissions to be used in residual-risk assessments and, where that requirement is not met, initiate a data-gathering effort supported by states and regulated parties. Initial data-collection efforts for screening assessments will need the cooperation of states, and data collection for refined risk assessments will require the cooperation of regulated parties. Data should be gathered during MACT development through the section 114 questionnaire and the information collection request, when collaboration with regulated parties is already taking place. Modifying Toxic Release Inventory reporting requirements so that what is reported is more consistent with data needs should be considered, such as reporting average emission rates, not total emissions in pounds.

3. Detailed Risk Assessments. If source categories considered in the screening risk-assessment phase are found to pose an incremental lifetime cancer risk that exceeds 10^{-6} for a reasonable upper-bound-exposed person in an affected population or if a noncancer hazard index—sum of the ratios of exposure concentrations of noncarcinogens to their Reference Concentrations (RfCs)—exceeds 10, the categories should be further classified. Those values are proposed as potential bright lines (see section 5.3), but some experience with source categories will be needed to see how well they serve in forming appropriate categories.

If a cancer risk is $\geq 10^{-4}$ or a noncancer hazard index is ≥ 10, the source category is considered to have high priority. More detailed risk assessments should be performed first within that category. Those risk assessments should be facility-specific and should be performed in partnership with regulated parties and other stakeholders as appropriate.

If a cancer risk is between 10^{-6} and 10^{-4} and a noncancer hazard index is less than 10, a source category is considered to have less-high or "medium" priority. Risk-assessment results should be distributed to the affected industries and other interested parties so that voluntary process changes or other actions can be evaluated to reduce emissions or risks associated with those sources.

4. Risk Reduction. Additional controls or process changes should be evaluated if more detailed risk assessments performed within source categories found to have high priority yield incremental lifetime cancer risks of $\geq 10^{-5}$ or noncancer hazard indices of ≥ 1 to reduce them to

below 10^{-5} or 1, respectively. If the more detailed risk assessments yield incremental lifetime cancer risks of $< 10^{-5}$ and noncancer hazard indices of < 1, no further action should be required. To the extent practical, when more than one source category of high priority is found at the same facility their risks should be evaluated together.

Identifying and implementing changes to reduce risk, where required, should be performed as part of a local or regional risk-management process conducted with the Commission's framework. Establishing risk-management goals with that framework should include consideration of not only the individual facility of concern, but also its context, including pathways of exposure to hazardous air pollutants besides inhalation (such as water or soil), the air-quality characteristics of the region, other sources of pollutant emissions, and considerations in addition to human health risk such as costs, benefits, equity, and values. The process must be conducted with full stakeholder participation.

5. Iteration. On the basis of learning from the risk assessments for the source categories considered by the agency to pose the greatest risks, the agency should determine the need for proceeding with assessments of medium-priority and low-priority source categories.

RATIONALE

Several aspects of the preceding scheme require elaboration.

Identification of High-Priority Source Categories

The Commission believes that EPA—through the experience gained during the first stages of implementing the 1990 amendments to the Clean Air Act, developing MACT standards, and setting priorities among hazardous air pollutants—has acquired enough information to identify the source categories most likely to pose residual risks. High-priority source categories should be identifiable on the basis of quantitative information, such as emissions data and how many people are exposed, where available, and also on the basis of qualitative considerations, such as whether high-priority hazardous air pollutants are present, whether there are sensitive subpopulations, and whether there are highly exposed populations, or "hot spots".

Screening Risk Assessments

Figure 6.1 describes a process whereby priority is given to sources likely to pose the highest risks. Subjecting source categories to a priority ranking requires the development of a screening risk-assessment model. Screening is based largely on some consistently applied estimate of exposure. At each step in the screening assesment, some decision must be made about the priority to give the categories and what actions to take. The Commission recommends integration of this screening process within its framework for risk management described in section 2.

Performing screening risk assessments at every facility within a source category would be

prohibitive, so a screening model that can be used to generalize risks for a source category or for types of facilities within a source category is needed. The screening model must be able both to account for differences among facilities and to provide results that can be used as a guide to making decisions about the need for further analysis. EPA should develop useful screening methods in partnership with state regulators and with input from regulated parties and other stakeholders.

Upper-end point estimates of exposure can be appropriate for screening risk assessments, but the use of the hypothetical maximally exposed individual (MEI) yields such an unrealistic overestimate of exposure that it should not be used (see section 3.2). Screening risk assessments should rely on more-representative estimates of exposure, such as EPA's "high-end exposure estimate" (HEEE) or an estimate based on a highly exposed actual person or reasonable worst case. More-detailed risk assessments should consider the entire exposure distribution (see section 3.2).

The goal of a screening risk assessment is to ensure protection of any especially susceptible subpopulations by using conservative assumptions to estimate toxicity, such as cancer potencies and RfCs. Detailed risk assessments should reflect the multiple pathways by which exposure to hazardous air pollutants can occur, obtain population- or ecosystem-specific exposure data to the extent feasible, and consider in more detail the health status of the community and specific population subgroups for health effects of particular concern.

Decision Threshold After Screening Risk Assessment

Within the decision-making framework, a threshold is needed to discriminate between sources that should be considered further and sources that need not. The Commission opposes the inflexible use of bright lines for regulation, but using a bright line to guide a decision-making process is necessary for efficient risk management.

The 1990 amendments to the Clean Air Act set 10^{-6} as the threshold for considering source categories for reduction of residual risk. Those with screening risk estimates that fall within the 10^{-6}-10^{-4} range might not require high priority because of the conservative nature of the assumptions used in screening risk assessments. The Commission therefore recommends that an intermediate category of "medium" priority be established for source categories with estimated risks between 10^{-6} and 10^{-4} on the basis of screening assessment. Sources that fall within that range might consider voluntary engineering improvements to reduce emissions and risk. Using a flexible 10^{-6}-10^{-4} approach is consistent with the permitting strategy already in place in a number of states, according to testimony received by the Commission from Joann Held and Tad Ahern, who manage air toxics programs in New Jersey and Maryland, respectively, where facilities within that range can negotiate their options.

The 1990 amendments do not set a threshold for considering health risks other than cancer, which the Commission believes to be a serious omission. We chose a threshold noncancer hazard index of 10 because there are few hazardous air pollutants with RfCs that are within a

factor of 10 of their no-observed-adverse-effect levels. A screening-level hazard index is calculated by dividing the exposure concentration of each noncarcinogen by its reference concentration (RfC) and then adding those ratios together. Detailed risk assessments might rely on several hazard indices, determined by adding together ratios only for chemicals with similar health effects.

Decision Threshold after Detailed Risk Assessment

The Commission prefers a 10^{-5} flexible bright line for actions to reduce residual cancer risk based on detailed risk assessments. That action level is consistent with Congressional guidance to use 10^{-6} for screening purposes. The choice of that decision threshold will be better informed after some experience is gained across source categories, including replacement of default assumptions with actual exposure data. Use of a threshold for action more stringent than a 10^{-5} lifetime upper-bound incremental cancer risk would continue an outdated practice of giving much greater attention to cancer risks than to all other health and ecological risks. In fact, within the Clean Air Act, there is a striking contrast between permissible margins of exposure for section 112 carcinogenic air pollutants and ubiquitous section 109 criteria air pollutants. For a lifetime upper-bound risk of 10^{-6}, the permissible margin of exposure for carcinogenic air pollutants is greater than 100,000-fold. For lead, carbon monoxide, small particles, and other criteria air pollutants, the permissible margin of exposure of recognized susceptible populations is below exposures associated with adverse effects by less than a factor of 2.

Section 112 addresses other serious hazards besides cancer, such as reproductive, developmental, and neurologic impairments. California's Proposition 65 labeling regulations similarly cover carcinogenic and reproductive effects. In that state, environmental activists and businesses accepted an agency decision to put the action level for carcinogens at 10^{-5} and the action level for reproductive toxicants at one thousandth of the no-observed-adverse-effect level. Those action levels for labeling apply to products to which very large numbers of people are likely to be exposed. For many section 112 source categories, in comparison, relatively few people are within exposure range of the point sources. Expressing risks in terms of numbers of persons who might be affected per year or per hypothetical lifetime, as well as the probabilistic estimates per 100,000 persons exposed, can help in risk communication (see section 5.1).

Risk Management

Implementing a tiered or phased approach to assessing risk, such as that recommended here and in *Science and Judgment in Risk Assessment* (NRC 1994), could lead to awkward public-relations circumstances. Situations might arise in which a community is told that a nearby facility might present a potential health risk, on the basis of a screening risk assessment, and is then assured, after a more detailed risk assessment, that the facility does not pose a threat. Members of the community are likely to remain suspicious and believe that the facility is hazardous despite messages to the contrary. Communicating iterative estimates of risk to the

public and the media without loss of credibility is extremely difficult and will require serious consideration in each case. EPA has a special responsibility to communicate that the purpose of a screening assessment is to separate sources that clearly pose negligible risks from sources that might pose higher risks and that screening assessments do not assess the magnitudes of likely risks. Early and regular stakeholder participation might reduce the likelihood of conflict; outrage often arises when affected parties are brought into the process late (although there can be additional interested parties at later stages).

When a facility is identified as having high priority and posing potential risks to health, a participatory, community-based approach to managing those risks should be used. Involving stakeholders in the risk-management process described in section 2 can identify additional factors that should be addressed, improve the quality of risk assessment, and increase the likelihood that the results of risk assessment and any decisions made with regard to managing risks will receive broad acceptance.

Application of the Commission's Risk-Management Framework to the Determination of Residual Risks

The Commission recommends that the risk-management framework described in section 2 be used to guide the design and implementation of strategies to address residual risks associated with sources subject to MACT standards. A goal of this framework is to involve stakeholders in the process early. As the process becomes more and more specific to local situations, however, so will the involvement of different stakeholder groups. For example, in the early stages of the process, when procedures for defining MACT subcategories and screening models are being developed, stakeholders might include the regulatory agencies, industries, and environmental or public-health organizations that address national issues. During later stages of the process, when the risks and risk-reduction options associated with individual pollutant sources are being considered, stakeholders might involve other participants from the community, such as health-care providers, plant managers, local politicians, and other citizens concerned about the outcome.

Problem/Context. Implementation of the decision tree for evaluating the problem of residual risks should begin by defining the scope of the national, regional, and local air-toxics problem. The public-health and environmental contexts include other sources of emissions of the same pollutants and risks associated with other regulated—and not-yet regulated—pollutants. The goal is to build a consistent understanding among stakeholders about the health context in which a particular pollution problem is being addressed and to provide guidance for the rest of the decision tree.

Risks. Once the problem is defined, the next stage of the process involves estimating the potential health risks associated with source categories that have implemented MACT. First, priorities are set among them. As of May 1996, 27 source categories had MACT standards. However, their relative hazard potential is largely unknown, and a process for identifying potentially high-risk sources has not been articulated. Including stakeholders at this stage

might involve establishing basic criteria for defining MACT subcategories and developing a strategy for obtaining the necessary information to perform a screening risk assessment. EPA could develop a draft plan and make it available to the public through a variety of mechanisms (e.g., dissemination through the Internet or through regional offices, state air agencies, and state environmental and health organization). Public dissemination could provide two benefits: obtaining input to the draft criteria-development and information-gathering strategy and identifying potential stakeholders for future steps in the process. Indeed, EPA is already working with state agencies to develop presumptive MACT standards; thus, the groundwork has been laid for expanding this effort during the stage of residual-risk determination in the hazardous air-pollutant program.

The goal of performing screening assessments of the MACT categories and subcategories is to determine whether they warrant further attention. The basis for the screening assessment is a screening model that relies on production, emissions, meteorologic, and demographic data. Peer review is necessary to ensure the integrity of the model among stakeholders. If the process of identifying MACT subcategories has been effective, there should be little disparity between the screening-model findings and the results from individual facilities. However, if a large number of sources have individual screening results that are either much higher or much lower than source-category screening model results, that could provide important risk-management information.

For sources identified as having high priority, a local stakeholder process would be set up—presumably from a subset of previously identified stakeholders—as well as newly identified participants. The stakeholder group would monitor the development and results of the detailed risk-assessment process. The group could provide useful input to the risk assessment and economic analysis by posing specific questions for the analysts to consider and by identifying exposure-assessment data needs and potentially vulnerable subpopulations.

Options. As in the risk-assessment stage of the framework, stakeholders could pose questions concerning economic impacts and technical details associated with various alternative options for pollution control or risk reduction. Care should be taken to ensure that the quality of this information is acceptable to the stakeholders, including use of peer review.

Decisions. Following the framework will not change the decision-making responsibilities of the regulatory agencies. However, the decision-making process should become better informed, include more explicit information on the costs and benefits of the actions chosen, and, if implemented properly, gain more public support than decisions that are made without stakeholder participation.

Actions. Traditionally, ensuring that actions are taken has been the responsibility of the licensing and enforcement divisions of regulatory agencies. Despite the importance of this activity, public involvement is generally at its lowest at this stage of the process. A solid oversight effort by stakeholders could ensure that actions are taken in a timely manner and are maintained and that implementation problems are properly identified and addressed.

Evaluation. In general, although there is often much criticism of risk-management decisions and actions, there is little evaluation. For example, was a decision responsive to the problem that was identified? Did the actions taken achieve the intended results? What recommendations could be made for addressing similar problems in the future? What were the critical information needs or gaps? Were the benefit and cost estimates reasonable?

It should be recognized that environmental risk management deals centrally with the need to make and implement decisions in the face of much uncertainty. If the overall process of risk management is to move forward, careful and thoughtful evaluation must take place. If done routinely and consistently, the results of such evaluations could provide valuable information concerning research needs and the development of better analytic methods, and could form the basis for improving the risk-management process as a whole.

* * *

FINDING 6.1.1.2: In carrying out its hazardous-air-pollutant program, EPA has attempted a decision-making mechanism that involves the regulated parties at the very early stages of the process. This mechanism, referred to as the MACT partnership program, is intended to optimize the amount of knowledge, skills, and resources devoted to the development of a MACT standard.

RECOMMENDATION: The partnership program should continue and be expanded to facilitate a stakeholder-based approach to setting MACT standards, including health and environmental organizations and community representatives. should establish an evaluation process for the partnership program. If it is found to be useful and effective, the Commission further recommends that it be used to facilitate decision-making related to residual-risk determinations.

RATIONALE

The hazardous-air-pollutant provisions of the Clean Air Act require EPA to promulgate standards for 174 source categories over a clearly defined timetable. The goal of EPA's partnership program is to reach decisions about MACT standards through a consensus-based decision-making process. Participants in this process hope that through a partnership framework, decisions can be made in a more timely and effective manner than has occurred thus far. At least points of disagreement could be identified and reduced. The Commission was told that use of the partnership program to facilitate decision-making shows promise in this regard, although a formal evaluation of the program is lacking.

Conceptually, the partnership approach appears to be preferable to other decision-making models. It is important to determine whether the decision-making mechanism can be improved, however, both to expedite the promulgation of standards and to yield starting points for issues concerning residual-risk determinations.

* * *

FINDING 6.1.1.3: Many emissions sources can be subject to multiple MACT standards, as well as to additional Clean Air Act provisions (such as those addressing ozone control), so the impact of multiple regulatory requirements must be considered.

RECOMMENDATION: EPA should continue its efforts to integrate multiple permitting requirements into a workable licensing system. In particular, it should consider adopting some regulatory flexibility for sources with multiple compliance schedules. This flexibility should focus on maximizing the cost effectiveness of pollution-control measures within a reasonable timeframe. It should also focus on the pollution-reduction benefit that a more-comprehensive regulatory program could achieve.

RATIONALE

Control of individual pollutants should not be considered in the absence of an overall regulatory context. Because MACT addresses existing sources, consideration should be given to the effects of multiple control requirements on the systems operating within a facility. Generic pollution standards for individual processes might neglect how the processes interact with other systems within a facility. They might also neglect the logistical problems that can arise when particular processes are modified. More-sophisticated policies for determining regulatory compliance are needed to address pollution-control issues associated with complex systems. Emphasis should be given to applying MACT throughout a facility with control-technology requirements and timelines set to optimize both the effectiveness and the efficiency of pollution-reduction measures. The partnership program should help facilitate an integrated approach.

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FINDING 6.1.1.4: Compared with extensively regulated outdoor air pollution, indoor air pollution can pose a substantial risk to human health. Yet, it receives little attention and remains largely unregulated. EPA's efforts to address indoor air pollution reportedly have been thwarted by its lack of statutory authority, by the lack of agreement on the nature of the problem and its solutions, and by the fact that jurisdiction over indoor air pollution is shared by several regulatory agencies.

RECOMMENDATION: Congress should direct EPA, OSHA, and other federal agencies to develop a coordinated strategy that addresses the growing problem of indoor air pollution. In developing this strategy, the agencies should consider implementing the Commission's risk-management framework as outlined in section 2 of this report. Until a coordinated regulatory strategy that addresses the problem of indoor air pollution is developed and implemented, EPA should continue to encourage the formation of building and safety committees to address indoor-air quality concerns.

RATIONALE

Over the last 2 decades, public-health attention has been drawn increasingly to the problem of indoor air pollution. The energy crises in the 1970s led to a lowering of fresh air ventilation rates recommended by the American Society of Heating, Refrigeration and Air Conditioning Engineers. Many building owners responded by lowering the amount of fresh-air circulation through buildings and adding insulation to the walls. Meanwhile, increasing quantities of products containing volatile chemicals were introduced into buildings, such as plywood and pressed-wood products and carpeting. The National Institute for Occupational Safety and Health (NIOSH) has reported many complaints, mainly of nonspecific symptoms, such as headache, nausea, and eye irritation. The lack of a clearly distinguishable constellation of symptoms and their causes within indoor environments, led to use of the term “sick building syndrome”.

In addition, specific indoor-air pollution problems have been identified or better appreciated over the last 2 decades. They include effects of environmental tobacco smoke, radon, asbestos, lead, and indoor allergens (e.g., mold and dust mites). Exposure to those pollutants is associated with clearly defined health effects, such as lung cancer and asthma. Legionellae and other infectious agents can live in air-conditioning ducts and other indoor, moist niches and cause outbreaks of infections, possibly in combination with chemical exposures.

There is no risk-management framework for addressing indoor-air pollution concerns. There are essentially no enforceable standards, and EPA’s regulatory attention is focused mainly on outdoor air, despite research findings on total exposures. The attention of the Occupational Safety and Health Administration (OSHA) is focused mainly on industrial environments. Meanwhile, problems in offices, public buildings, and homes remain relatively unrecognized and unaddressed. Both agencies recognize the growing importance of the problem, but neither has the regulatory mandate to address it fully. There is an interagency task force that has begun to address the problem but it, too, lacks a statutory mandate.

Approaches to indoor-air pollution assessment and education generally remain fragmented at both the federal and state levels. EPA’s Office on Radon and Indoor Air Quality provides educational materials, and EPA coordinates indoor-air research efforts on an intra-agency and interagency basis. NIOSH continues to be active in surveillance. However, there is much political opposition to the development of a regulatory program: a recent OSHA public hearing on restricting smoking in the workplace and developing basic ventilation requirements was strongly dominated by the tobacco industry and various building-owner organizations.

Indoor air-quality problems are often complicated by their complexity and by their wide variation from one building to the next. Despite the differences, however, some guidance exists that can help to address these problems. EPA has produced excellent documents that can provide useful information. For example, the agency produced a kit called “tools for schools” that provides schools with much-needed assistance in addressing indoor air-quality problems. The agency could gain valuable risk-management expertise in this area as it

provides technical assistance to building committees organized to address indoor air-quality concerns and conducts evaluations of the effectiveness of their activities.

6.1.2

Superfund

When Congress enacted the original Superfund statute (Comprehensive Environmental Response, Compensation, and Liability Act, or CERCLA) in 1980, few were aware of the extent of the problem created by years of inappropriate or inadequate hazardous waste disposal practices. Many thought that the program would need to clean up just a few hundred sites, and expected the initial authorization of $1.6 billion plus reasonable expenditures by private companies to be sufficient and the cleanup to be quick. Today, we recognize that we must still address several hundred thousand contaminated sites, a legacy of an earlier industrial era. We also recognize that most of those sites are not so highly contaminated or complex as to require the attention and active management of the federal Superfund program. EPA, states, and others are working together on a range of approaches to address this wide array of contaminated sites. In particular, there is greater focus on brownfields created by the stigma of contamination that can be restored and employed in the local economy. Many states now administer voluntary cleanup programs that can efficiently return contaminated lands to productive reuse. Nonetheless, the shadow of liability under the Superfund statute hangs over all those sites.

Over the years, EPA has identified more than 40,000 potentially contaminated sites in its Comprehensive Environmental Response, Compensation, and Liability (CERCLIS) database. After site-specific evaluations, EPA recently announced that more than 27,000 of those need no further federal attention—a step that should assist in removing them from the liability shadow. The federal government and the states continue to study, design, and carry out cleanups at the remaining 13,000 sites on the CERCLIS data base. To date, about 1,300 of the 13,000 have been placed on the National Priorities List (NPL) for federal attention, and just over 25% of the 1,300 have been cleaned up. Although each of the last 2 years has produced more completed cleanups than the entire first decade of the program, progress is slow. With an average cleanup cost of $30 million per site, it is also very expensive. As Clean Sites Inc President Toby Clark has testified before Congress, usually someone is happy when Congress causes billions of dollars to be spent; almost everyone, however, seems disappointed with Superfund, for diverse reasons.

The 1990 amendments to the Superfund National Contingency Plan (NCP) addressed the competing goals of the 1986 Superfund Amendments and Reauthorization Act (SARA) by establishing a site-specific decision process. Under this process, cleanup options must satisfy the threshold criteria of protecting human health and the environment and comply with the applicable or relevant and appropriate requirements ("ARARs") of other federal and more stringent state environmental laws. Tradeoffs among options that meet the threshold criteria are then balanced with respect to seven additional criteria that reflect the SARA's mandates to "utilize permanent solutions . . . and treatment technologies to the maximum extent practicable" and to be cost-effective. Neither SARA nor the NCP prescribes in detail how to ensure "protection" or how to compare or match options for the protection of health and the

environment. Indeed, cleanup decisions often have to satisfy competing criteria in the statute and the NCP, such as long-term effectiveness and permanence of remedy; reduction of toxicity, mobility, or volume; short-term risks (especially to workers); and costs. Acceptability to states and communities is also a relevant criterion.

In the years since promulgation of the NCP, EPA has put into place several rounds of administrative reforms to achieve a "faster, fairer, more efficient" program and address "worst sites first" under the constraints of the current law. In the last few years, EPA has emphasized the importance of using reasonably anticipated future land use in site-specific risk assessments and cleanup decisions; issued several important groundwater guidance statements to implement recommendations of the National Research Council; acted to protect small parties, prospective purchasers, and innocent landowners from liability; instituted a risk-based priority-setting scheme for funding cleanup actions; and accelerated cleanups through, for example, presumptive remedies and the Superfund Accelerated Cleanup Model. It has also initiated the Brownfields Action Agenda and its pilot program, which seeks to empower states, communities, and other stakeholders through economic redevelopment, safe cleanup, and sustainable reuse of contaminated properties. EPA must face the challenge of implementing these improvements and goals consistently in its 10 regions and in states, territories, and tribal jurisdictions and ofmeeting reasonable expectations for cost effectiveness.

There is also a critical link between Superfund, the cleanup program for hazardous waste sites no longer in use, and the Resource Conservation and Recovery Act (RCRA) for management of wastes currently being generated. Designing Superfund cleanups and corrective actions under RCRA to comply with applicable requirements for the treatment, storage, and disposal of RCRA hazardous waste has been difficult. Guidance on using treatability variances to comply with land-disposal restrictions and more-recent regulations governing Corrective Action Management Units (CAMUs) help, but compliance is still too complex.

FINDING 6.1.2.1: Superfund can be said to have caused more frustration than any other environmental, health, or safety regulatory program, because of unexpectedly large numbers of sites, high costs associated with clean up of individual sites, high transaction costs caused by disputes about responsibility and liability, excessive delays, and until recently, a limited number of sites cleaned up. Some remedies have been technically ineffective or so expensive as to be financially punitive. Remedy selection has not consistently considered future uses or realistic exposure scenarios. In contrast, the highly successful emergency removal actions of Superfund are not well appreciated, despite its timely and major contribution to reduction of public-health and ecologic risks.

RECOMMENDATION: Risk assessments and remedy selection should be based on reasonably anticipated current and future uses of a site. As EPA's Land Use Directive of 1995 states, reasonable assumptions about future land uses should be developed early in a process of seeking consensus with local officials and community representatives, Congress should encourage reuse of brownfields, those sites in urban areas where economic use is avoided because of liability concerns. Also, Congress should grant EPA broader authority to develop

enforceable institutional controls.

RATIONALE

Land-use and other resource-use assumptions play a critical role in determining how clean a site must be for adequate protection of health and the environment which is one primary criterion under the Superfund NCP. A playground and an industrial warehouse are associated with very different potential-exposure scenarios and therefore need different remedial approaches with potentially differing costs to achieve the same estimated level of health protection. EPA's administrative actions and pilot projects to promote the reuse of brownfields include guidance documents about early consideration of future use, extensive coordination with communities and other stakeholders, deferral of NPL listing determinations while states oversee response actions, voluntary cleanup programs, and model agreements for purchasers.

Inclusion of affected communities from the start as partners in the investigation and remedy-selection processes, although it might seem to impose an additional step and concomitant delay, can improve the likelihood that the choice of remedy will reflect reasonably anticipated uses of the site and wishes of the community and reduce the dissonance and long delays often observed if goals and costs are debated only after EPA has proposed a remedy. Such a process is consistent with the Commission's risk-management framework.

Use of enforceable institutional controls, such as hazardous-substances easements, can make it feasible to protect health and the environment reliably into the future at cleanup levels that are less stringent than residential levels. For example, thoroughly cleaning up of a former industrial site in an urban area to a standard safe for young children would be unnecessary and might be so expensive as to preclude redevelopment. Such redeveloped sites might provide economic-development opportunities in depressed areas and save pristine areas elsewhere. Assurances for non-NPL sites that brownfield development under qualified state programs will protect cooperating prospective purchasers from Superfund liability must be accompanied by a continuing monitoring program so that potentially hazardous migration of contaminants from a site can be predicted, detected, and remedied before substantial risks to health or further environmental contamination can occur. Hazardous on-site exposures due to changes in land use or failure to control access must also be prevented.

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FINDING 6.1.2.2: EPA needs additional guidance about choosing risk-based cleanup standards. Remedy selection and cleanup standards are complicated by innumerable and sometimes conflicting ARARs (applicable or relevant and appropriate state, or other federal requirements), including state legal requirements to clean up to "background."

RECOMMENDATION: EPA should continue to use its $10^{-6} > 10^{-4}$ risk range as a guide for site-specific risk-based cleanup goals. Site-specific data from the Remedial Investigation/Feasibility Study process should be used to refine default assumptions when

available. Because a risk estimate is a result of many assumptions and judgments about choice of data sets, it is wise for Congress to eschew setting specific risk levels, leaving that decision to EPA and the states. The Commission prefers qualitative language in legislation, such as "reasonable certainty of no significant harm." The ARAR provision of the Superfund law should be amended to delete the "relevant and appropriate" language because it is subject to wide differences in interpretation, while retaining "applicable requirements."

RATIONALE

The risk range is being used productively by EPA. We recommend realistic high-end exposure scenarios for screening assessments and descriptive or probabilistic distributions or ranges of exposure for refined risk assessments (see section 3.2).

There has been too much confusion and conflict over the ARAR provision and little use of the ARAR-waiver clause. The state and federal regulations that can serve as ARARs were often not written for conditions at Superfund sites, and they greatly complicate remedy selection and implementation. We support retaining applicable state and federal requirements as long as they do not conflict with the risk-based goals tied to future land use, as recommended in the preceding section.

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FINDING 6.1.2.3: There are many difficulties in the implementation of the balancing criteria of the National Contingency Plan for Superfund. For example, the requirements introduced in SARA in 1986 to "utilize permanent solutions and . . . treatment technologies to the maximum extent practicable" have been applied inflexibly at some sites. Especially at nonresidential sites, interruption of exposure pathways and other controls might be more appropriate than treatment. Worker protection and cost containment require more attention.

RECOMMENDATION: The mandate to use permanent solutions "to the maximum extent practicable" should be changed in the law to assurance of long-term reliability of protection of health and the environment. The preference for using treatment for the reduction of toxicity, mobility, or volume as a principal element should be targeted at highly hazardous material to ensure long-term reliability and should be overridden when no effective treatment remedy is available. EPA should continue to develop better mechanisms for proper compliance with RCRA hazardous-waste standards at Superfund and RCRA corrective-action sites, such as the Hazardous Waste Identification Rule for contaminated media. A design-team approach, including states and responsible parties, should be encouraged to accelerate the remedial-design phase of the cleanup. Remedies should be chosen to be most cost-effective in meeting necessary protective cleanup levels.

RATIONALE

EPA, the states, potentially responsible parties, and citizens often are timid about applying on-

site remedies that reduce toxicity, mobility, or volume of contaminants— incineration, solidification, vapor extraction, and bioremediation— and about restrictions on use. Remedies involving removal to "elsewhere," usually landfills or off-site incinerators, generally are high-cost remedies and often are resisted by local communities anxious about numerous truck trips to haul away contaminated material or fearful of incineration and incineration malfunction. Parties must be encouraged to negotiate phases of cleanup, especially when even expensive remedial actions are inadequate for some aspects of the site, such as 30 - 50 years of pumping and treating groundwater contaminated by dense nonaqueous-phase liquids or construction of major terrain changes. On-site technologies that reduce toxicity, mobility, or volume should be used when appropriate. They should not be labeled as "innovative," which is a kiss of death for decision-makers; instead, they should be identified as EPA has begun to do, as "presumptive remedies" for appropriate sites and cleanups. Responsible parties should be given opportunities to propose and select alternative remedies if those remedies can meet overall cleanup objectives— including risk-based or residual contaminant or exposure levels— agreed on through a process open to public scrutiny. The least-expensive remedy is not always the most cost-effective; multiple health and ecologic effects might need to be balanced, as might community cultural, social, and political factors.

One aspect of the law that makes implementation of Superfund cleanups especially difficult is RCRA land-disposal restrictions, which discourage intrasite movement of wastes for less-intensive—yet efficient—treatment on-site. EPA has taken steps to reduce the problem via its Corrective Action Management Unit Rule and soon through its Hazardous Waste Identification Rule for contaminated environmental media, but the 104th Congress should remove the impediment to effective and efficient cleanup. Enactment in April 1996 of H.R. 2036, the Land Disposal Program Flexibility Act, provides a platform for complementing RCRA remediation reforms.

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FINDING 6.1.2.4: Superfund program costs have exceeded billions of dollars over 15 years and will increase. A budget process is needed to assure taxpayers and consumers that costs are being controlled. In general, decisions seem to be made without consideration of the aggregate effects, as though the capacity of taxpayers and consumers to support the federal and industry costs, as well as costs of responsible municipalities, is unbounded.

RECOMMENDATION: The entire national Superfund program— whether funded from the Superfund, private parties, municipalities, or some combination of those sources— should have an overall annual budget estimate so that Congressional appropriation and taxation decisions and EPA program actions can be better informed on a national scale. EPA's recently initiated risk-based allocation of cleanup funds should be developed for use in a budgeting and regulatory-impact analysis.

RATIONALE

The Commission believes that decentralized decision-making in regional EPA offices and in various states under authorized programs or Superfund cooperative agreements has led to many impractical and unduly expensive remedies, inconsistency, and limited learning from experience. Because potentially responsible parties must cover the costs of many remedial actions, there is little incentive for federal and state agencies to define a maximal cost when the record of decision (ROD) is made.

In the Bush Administration, EPA Administrator William Reilly proposed a "worst risks first" approach, but implementation has been inconsistent. Current EPA Administrator Carol Browner's policy and program initiatives have helped but could be enhanced by an assessment of aggregate needs and priorities. It will be difficult to propose and implement a budget plan for Superfund. The DOE Environmental Management Program constitutes an emerging example.

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FINDING 6.1.2.5: Once a record of decision (ROD) has been issued at a Superfund site, it has been difficult to revise the remedy selection, even when better and cheaper remedies have been identified later. In addition, changing policies on consideration of future land use could make it possible to alter the remedy in favor of a less expensive and smaller risk reduction.

RECOMMENDATION: EPA should expand and implement its new policy directive to address some general problems in older RODs. The agency should initiate changes in those RODs, or in response to petitions, and establish criteria for selective revision of RODs for particularly inappropriate remedies required in the past.

RATIONALE

EPA should establish procedures to provide appropriate and efficient redress of remedial actions in existing RODs in certain limited cases, such as land-use restrictions, development of important new scientific information, or technologic advances. Companies and communities that invested in cleanup of NPL sites during the first 15 years of a steep learning curve for EPA and the nation should receive the benefits new information and new technology can bring. For example, reassessment of 30 - 50 years of pumping and treating of groundwater after initial reduction in contamination levels seems appropriate for reopening RODs. Protections must be included to avoid an avalanche of petitions to an agency without sufficient resources to respond and to avoid triggering unintended litigation. The Commission is encouraged by EPA's "remedy update" reform currently being implemented administratively. This effort is targeted primarily at bringing older groundwater RODs up to date with current science and technology regarding appropriate cleanup objectives for different types of contamination problems, such as containment and removal of dense nonaqueous-phase liquids.

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FINDING 6.1.2.6: There is a continuing need for information and education on the toxicity of various chemicals, physicochemical characteristics of contaminants, sources of exposure, and effectiveness of remedies.

RECOMMENDATION: Congress should continue to support essential support programs for Superfund—the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute of Environmental Health Sciences (NIEHS) Superfund Basic Research Program at universities, NIEHS programs for training for hazardous-waste workers training programs and applicable EPA research and demonstration activities. The Superfund program should make greater use of EPA's own Science Advisory Board. If, as expected, more responsibility and funding for site-specific decision-making are delegated to the states, research and public-health assessment functions should continue to have high federal priority.

RATIONALE

Despite extremely challenging deadlines and inadequate data at many sites, ATSDR has made a valuable contribution to the Superfund program through its toxicological profiles of various common contaminants at Superfund sites, its public health advisories (in collaboration with local and state health departments), and its establishment of several exposure registries. That work should continue. The Superfund basic-research program administered by NIEHS under the Superfund appropriation has mobilized highly relevant interdisciplinary research at 17 universities. If Congress and the American people want risk estimates and remedies that are based on sound science, not default assumptions, support for research programs that address them is critical and is a federal responsibility. Good science does not of itself lead to application; Congress must also support EPA's research activities. Similarly, worker training and worker protection for the relatively high risks involved in the clean up of sites are continuing responsibilities.

EPA's Technology Innovation Office has a private-public partnership program coordinated by Clean Sites involving major companies with Superfund responsibilities, vendor companies with new or not widely used technologies, DOE or Department of Defense facilities, and state regulators. The program's demonstrations provide objective comparative assessments in real-world circumstances. They should be expanded, and their findings should be widely disseminated.

6.1.3

Office of Prevention, Pesticides and Toxic Substances

The authority and mandates of the Office of Prevention, Pesticides and Toxic Substances (OPPTS) are included in the Pollution Prevention Act, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA), and the Toxic Substances Control Act (TSCA). The subject of pollution prevention is discussed in section 5.4 of this report. This section focuses on issues related to the toxicity and registration of pesticides and on toxic substances.

FINDING 6.1.3.1: When EPA is precluded by the "Delaney clause" from issuing a tolerance for a pesticide, that pesticide cannot be used on a crop even if it meets all the requirements for registration under FIFRA and for a tolerance under section 408 of FFDCA. Thus, the Delaney clause effectively pre-empts the risk-benefit framework for regulation established in FIFRA and section 408 of FFDCA.

RECOMMENDATION: Pesticides should be exempted from regulation under section 409 of FFDCA and be regulated solely under FIFRA and section 408 of FFDCA. The standard of protection specified in section 408 should be changed to "reasonable certainty of no harm" in keeping with the Food and Drug Administration's well-established statutory language. At the same time, the safety standard should be improved to allow for advances in scientific understanding and by requiring the consideration of potential highly exposed populations such as children.

RATIONALE

Together, FIFRA and section 408 of FFDCA establish risk-benefit comparison as the basis for pesticide regulation. Section 3 of FIFRA states that the administrator of EPA shall register a pesticide, provided that, among other requirements, "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment" [section 3(c)(5)(D)]. "Unreasonable adverse effects on the environment" is defined in section 2 as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" [section 2(bb)].

Section 408 of FFDCA provides requirements for establishing tolerances for pesticide residues in both raw agricultural commodities and processed foods. When a pesticide residue concentrates in processed food to greater than its section 408 tolerance concentration for the raw agricultural commodity, however, the processed-food tolerance is established under

section 409 of FFDCA. Section 409 (and not section 408) contains the Delaney clause, which is a proviso to the general safety standard. The Delaney Clause provides that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." Interpreted literally, the Delaney clause requires application of a zero risk standard, which precludes consideration of risks and benefits. In practice, a pesticide can meet the standard for a tolerance under section 408, but can't be granted one if it is banned completely from processed foods under section 409 (the "Delaney paradox").

The conflicting requirements for pesticide regulation under FIFRA and FFDCA are not always in the interests of public and environmental health. Pesticides should be uniformly regulated according to risk-based standards and risk-benefit comparisons, such as those already provided for under FIFRA and section 408 of FFDCA. These issues are addressed more broadly in section 6.3 of this report, which focuses on the FDA.

If pesticides are to be regulated solely under FIFRA and section 408 of the FFDCA, Congress should also consider improvements to the existing safety standard. The standard should be flexible enough to account for changes in scientific understanding and to address emerging risk issues. For example, the National Research Council report *Pesticides in the Diets of Infants and Children* (NRC 1993) concluded that current tolerance-setting practices might not adequately protect children. The safety standard in section 408 of the FFDCA should be amended to require appropriate agency actions to ensure the adoption of the key recommendations of the NRC study.

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FINDING 6.1.3.2: Historically, EPA has made its regulatory decisions chemical by chemical, including pesticide-registration decisions. That approach does not accommodate consideration of the potential effects of exposures to several chemically different pesticides with similar effects or of multiple exposures to chemically similar pesticides. EPA considers multiple exposures and multiple risks when it evaluates pesticides for the purpose of reregistering them, but it does not yet do so during the evaluation of new pesticides.

RECOMMENDATION: EPA should establish an integrated approach to the registration process to evaluate multiple risks and exposures to multiple agents and to compare the risks and benefits associated with alternatives, provide a more complete evaluation of exposures and risks. Furthermore, to encourage development of safer pesticides and reduction in the use of more hazardous alternatives while avoiding market disruption, EPA should expand its accelerated registration program for the products that meet rigorous and well-defined criteria for high human-health and environmental-safety standards. Products that meet the high standards should be permitted to carry EPA-approved labels to communicate to the user that they meet high safety standards.

RATIONALE

EPA has avoided using an integrated approach to registration, because of the potential for serious disruption of market forces, such as shortages due to the loss of minor-use labels important to fruit and vegetable growers and pesticide-resistance problems as the number of pesticide products on the market is reduced. Instead, the agency has encouraged the substitution of biologic pesticides for more hazardous chemicals and the use of formulation changes and equipment modifications to decrease exposure. It has canceled some of the uses of pesticides that are particularly hazardous, such as parathion. And it has established a restricted-use category for needed but highly toxic pesticides to ensure that they will be used only by pest-control operators and agricultural workers qualified by training and experience to use them properly. For the agency to improve the rational use of pesticides and minimize their adverse effects by establishing an integrated approach to evaluation of multiple risks and of exposures to multiple agents, the agency should introduce the new approach on a demonstration basis, to avoid disruption.

EPA has a long-standing commitment to developing safer pesticides and alternatives to chemical pesticides. By creating a safer pesticide-registration and pesticide-labeling program, EPA can encourage development of safer alternatives and elimination of highly hazardous materials. A pesticide registration and labeling policy would give manufacturers an incentive to develop safer alternatives and and give consumers information on which to base informed choices. The marketplace can operate to reduce or eliminate exposures without the disruption and spot shortages that can be caused by an integrated approach.

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FINDING 6.1.3.3: In recent years, review requirements for new chemicals and advances in the understanding of chemical toxicology have made important contributions to a lower incidence of new findings of carcinogenicity and other adverse effects among chemicals marketed. The Toxic Substances Control Act (TSCA) has not been reauthorized since its enactment in 1976, however, and EPA is mostly limited to review of data submitted, without being able to specify what studies should be conducted.

RECOMMENDATION: TSCA should be updated to reflect advances in toxicology and regulation over the last 20 years. Congress and EPA should clarify what kinds of toxicity, clinical, and exposure data should be generated as required under section 4 and reported under section 8 of TSCA.

RATIONALE

To help EPA with the continuous review of chemicals, manufactureres are responsible for reporting studies and other information that indicates the likelihood of adverse effects associated with their products. However, the extent of company responsibilities for reporting information on chemicals proposed to be marketed and chemicals not further developed is not

always clear. EPA/OPPTS is seeking to clarify both under TSCA 8(e) and FIFRA 6(a)(2) what studies and human adverse-event reports must be submitted to the agency.

OPPTS should devise means of analyzing technical information submitted under section 8, to address generic scientific and policy questions. For example, does use of a second species in toxicology tests add sufficient information to influence risk-management decisions? Are there biologically important correlations between the occurrence of tumors and other end points? TSCA potentially could provide a richer database than the National Toxicology Program (NTP), although without the systematic quality control of NTP bioassays. An analysis of new and old data that are required to be submitted under section 8(e) and 8(d) should be a joint effort of OPPTS and the Office of Research and Development/NCEA. Requirements to test chemicals have seldom been imposed; the threshold for issuing such a test rule is considered to require more extensive data than are available to justify it. Together, EPA and Congress should clarify section 4. Companies are required under TSCA 8(c) to retain files with reports of health effects in people exposed, but are not required to submit such files. EPA, industry, academics, and worker and consumer representatives could be brought together to propose criteria for making use of such information, relating it to use and exposure data to generate estimates of incidence rates, and developing practical analogies to the FDA adverse drug reaction reporting and analysis scheme.

The OECD recommends a basic set of testing requirements for new chemicals that are to be introduced to the market in member countries. Testing requirements are tiered and increase as the market for a product develops. Given the limitations of EPA's ability to require testing under TSCA and the absence of data accompanying new submissions, Congress should consider providing EPA with similar authority to specify what studies should be conducted by the manufacturer.

EPA is expected to propose testing protocols and testing requirements for effects of chemicals on endocrine functions, especially estrogenic, anti-estrogenic, and androgenic effects. At the first meeting of the Commission in May 1994, we invited Theo Colburn to discuss observations in wildlife, fish, and humans of changes in reproduction, gender-specific behaviors, sperm count, and incidence of anomalies of the genitalia. The terms "endocrine disrupters" and "endocrine modulators" have emerged as descriptive of a wide range of such effects (Davis and Bradlow 1995, McLachlan and Korach 1995, Colburn et al. 1996). Some, but not all, are mediated by or attributed to compounds that bind to estrogen receptors. Some are chlorinated compounds, but many others are not (alkylethoxylate plasticizers, for example).

Many scientific issues related to endocrine "disruptors" are just being framed. This topic stands at the hazard-identification stage of the risk-assessment framework (section 1) and the problem/context stage of the Commission's risk-management framework (section 2): How do agonists and antagonists interact (estrogens and antiestrogens)? How predictive are the complex endocrine assays? How do we estimate risks associated with exposure to very low doses of environmental estrogenic chemicals when dietary doses of naturally occurring

estrogenic compounds (phytoestrogens, such as flavonoids) are so much higher? Even higher than dietary doses of estrogenic chemicals are ingested in the form of oral contraceptives and post-menopausal hormone replacement therapy. The National Research Council has established the Committee on Hormone-Related Toxicants in the Environment to assess their known and suspected modes of action and potential toxicity and impacts on wildlife and humans. EPA's Health Effects Research Laboratory has been working to identify those modes of action for some years. And the Chemical Industry Institute of Toxicology has announced that a portion of their budget has been reallocated to initiate a program of research on endocrine effects.

The Commission supports giving priority to the scientific assessment of the potential toxicity of this class of chemicals.

6.1.4

Office of Water

The EPA Office of Water has responsibility for protecting the nation's surface water and groundwater and ensuring the supply of safe drinking water for the public. The Clean Water Act was enacted in 1972, soon after the dramatic incident in which the Cuyahoga River in Ohio caught fire because it was so polluted. Water quality has improved substantially since then. Nevertheless, about 35% of America's surveyed rivers, lakes, and streams still do not meet standards for their designated uses (OECD 1993). Point sources of pollution have been controlled to a great extent; now state water-quality managers have identified nonpoint sources, such as urban and agricultural runoff, as the largest contributors to water-quality problems.

The Clean Water Act regulates point-source and nonpoint-source discharges of pollutants to the waters of the United States. States establish water-quality standards based on the designated use of a water body—such as providing fish for consumption, agriculture, or drinking water—and on the quantitative or narrative water-quality criteria that are required to support a particular use. Point sources obtain permits for discharges based on available treatment technologies and on the quality of the water receiving the discharge and its designated use. Effluent guidelines for a particular point source are based on either available technology or water quality. Technology-based effluent guidelines set a consistent, industrywide level of control and are imposed at the point of discharge; if they prove to be inadequate to meet the water-quality standards for a particular body of water, additional controls are implemented to meet effluent limits based on water quality. Effluent limits have been established for over 100 pollutants discharged by 51 categories of industry and are based on the best available technology that is economically achievable. For nonpoint sources of water pollution, states use grants from EPA to develop control programs, usually providing for implementation of best management practices.

The Safe Drinking Water Act of 1974 as amended requires EPA to set drinking-water standards to protect human health from both naturally occurring and anthropogenic contaminants, and it specifies requirements for water treatment. Standards have been formulated for more than 80 contaminants. For each regulated pollutant, EPA publishes an unenforced maximum-contaminant-level goal based solely on health considerations and promulgates a standard that includes both health and feasibility considerations. Feasibility is determined by considering available technology and cost. The importance of safe drinking water was driven home in April 1993, when *Cryptosporidia* in the Milwaukee water supply caused an epidemic resulting in death and severe intestinal disorders.

The following recommendations are intended to build on the important improvements of the last 25 years in surface water, groundwater, and drinking water.

FINDING 6.1.4.1: The Clean Water Act regulates sources of pollution in a manner that has resulted in fragmented programs that do not adequately address the health of the watershed ecosystem or sufficiently involve communities, states, and others in multijurisdictional management and protection of water quality.

RECOMMENDATION: The Clean Water Act should be amended to establish a comprehensive, integrated watershed-management approach that uses ecological risk assessment and biotic-integrity measurements and to provide for the development of state watershed programs. The state programs should be subject to EPA approval and oversight and have substantial involvement by stakeholders and other appropriate federal, state, and local agencies.

RATIONALE

Over the last 25 years, pollutant discharges into the nation's rivers, lakes, estuaries, coastal waters, and wetlands have been greatly reduced. Much of the success has been achieved through the control of municipal and industrial point-source discharges into water bodies under programs established by the Clean Water Act. However, the health of an aquatic ecosystem can be affected not only by point sources of pollution but also by nonpoint sources such as urban and agricultural runoff. And it can also be affected by activities that disturb the land, including logging and grazing, construction (especially of dams and reservoirs), diversion of surface-water and groundwater flows for domestic and agricultural uses, overfishing, introduction of exotic species into water bodies, and deposition of air pollutants. Russell Jim of the Yakama Indian Nation spoke to the Commission about the contribution of several of such phenomena to the decline of salmon populations in the Pacific Northwest. The clean-water programs take a fragmented approach to those problems and do not provide for integrated environmental management of the watershed ecosystem. With a watershed-management approach, ecosystems and human health could be better protected from the cumulative effects of a multitude of natural and human activities.

The watershed-management approach is a comprehensive, geographically based approach that recognizes all resources within a hydrologically defined watershed as parts of an interconnected system that depends on the health of the parts to sustain the healthy functioning of the ecosystem. Ecological risk assessment and the index of biotic integrity (see section 3.4) can be important tools in identifying stressors of the watershed and characterizing their impact on various plant and animal species. For example, ecological risk-assessment case studies being examined by the Office of Water include a wide array of ecological organization, including individuals, communities, habitats, landscapes, ecosystems, and combinations of these. The watersheds examined include the Snake River, the Middle Platte River, Waquoit Bay, and Big Darby Creek.

Watershed management should focus on identifying priorities and tailoring solutions to the specific set of problems found in a watershed. The estuary programs in Tampa Bay and Galveston Bay are good examples of state- and local-governments and citizen participation in a process that identifies high-priority environmental problems for the estuaries and institutes

action to ameliorate the problems. Those two programs are also good examples of a multimedia approach to environmental problems, in that atmospheric deposition was found to be an important source of potential water pollution in both locations.

Achieving greater efficiency and effectiveness through watershed management will depend on building partnerships and integrating federal, regional, state, tribal, territorial, local, and private programs within the watershed.

* * *

FINDING 6.1.4.2: Regulation of water pollution under the Clean Water Act is implemented generally through effluent limits based on technology and water quality. Ecologic and human-health risk assessments provide information that is used to help set effluent limits based on water quality and criteria for receiving-water quality. Risk assessments are also used to set regulatory priorities.

RECOMMENDATION: EPA and the states should continue to use receiving-water quality and risk-assessment results (and other considerations) to set priorities for the development of various water-pollution control programs. Risk assessment should also be used, where appropriate, to establish water-quality criteria and effluent limits based on water quality. However, risk-based effluent limits should not yet supplant technology-based and quality-based techniques for reducing water-pollutant discharges and protecting water quality.

RATIONALE

Risk assessment provides useful information for making decisions about the best ways to control water pollution. EPA uses human-health risk assessment to derive water-quality criteria intended to protect human health. In contrast, ecologic risk assessment is not yet likely to afford adequate descriptions of risks to complex aquatic systems (see section 3.4). For example, the impacts of endocrine "disruptors" on fish and on the offspring of fish-eating animals have not been fully assessed. As an emerging tool, ecological risk assessment has not yet reached the level of sophistication and reliability necessary to support its use as the primary determinant of effluent limits based on water quality.

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FINDING 6.1.4.3: Methods to assess microbial risks associated with drinking water are too limited for general use, and data on risks associated with microorganisms, disinfectants, and disinfection byproducts are sparse.

RECOMMENDATION: EPA should give a higher priority to the improvement and application of methods for assessing waterborne microbial risks and to the development of data for assessing relationships among the occurrence of microbial contamination, the use of disinfectants, and the formation of potentially hazardous disinfection byproducts.

RATIONALE

Evaluating drinking-water quality includes assessing both microbiologic risks and risks associated with disinfectants and disinfection byproducts. Microbiologic contamination of drinking-water supplies poses a clear threat to public health when treatment is inadequate. In response to the threat, EPA is developing a risk-assessment paradigm for evaluating human risks associated with waterborne pathogens. Efforts to reduce potential health risks associated with disinfection byproducts must not compromise the microbiologic quality of drinking water.

A 1992 regulatory negotiation effort has recently produced the Information Collection Rule, which establishes monitoring and data-reporting requirements for large public water systems for EPA to use in setting various drinking-water standards. Implementation of the rule is hoped to lead to greater understanding and better characterization of the risks associated with microorganisms, disinfectants, and disinfection byproducts. Additional data and analysis of those risks are needed before new drinking-water standards are promulgated. Because implementing new standards is expensive and because a large proportion of the United States population is exposed, research should be focused on characterizing risks related to different disinfectants and disinfection byproducts and comparing them with microbial risks so that the agency can target its activities toward the greatest potential risk reduction.

6.2

Occupational Safety and Health Administration and National Institute for Occupational Safety and Health

An estimated 60,000 deaths every year in the United States are related to occupational disease and injury. In 1994, occupational injuries alone were responsible for an estimated $120 billion in lost wages and productivity, administrative expenses, health care, and other costs, although the annual occupational fatality rate has been reduced from 18 per 100,000 workers in 1970 to 8 per 100,000 in 1993. The Occupational Safety and Health Administration (OSHA), established in 1970 as a part of the Department of Labor, was charged with the responsibility of reducing worker injury, illness, and death caused by workplace hazards and exposures to toxic substances and harmful physical agents. The Occupational Safety and Health Act of 1970 directed OSHA "to assure so far as possible every working man and woman in the nation safe and healthful working conditions." That is to be accomplished by several means, including "providing medical criteria which assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience and providing for the development and promulgation of occupational safety and health standards". The mandate specifies that workplace standards that OSHA promulgates must be economically feasible, be technologically feasible, and have demonstrable benefits.

The National Institute for Occupational Safety and Health (NIOSH) was established by the Occupational Safety and Health Act as a part of the Department of Health and Human Services to conduct scientific research in occupational safety and health; to develop innovative methods, techniques, and approaches for addressing problems in occupational safety and health; to train a workforce of professionals in occupational safety and health; and to make recommendations to OSHA about standards for occupational safety and health. NIOSH identifies the causes of work-related diseases and injuries and the potential hazards of new work technologies and practices. With this information, it determines new and effective ways to protect workers from exposure to toxic substances, harmful physical agents, machine- and equipment-related hazards, and hazardous working conditions.

FINDING 6.2.1: The nation's recordkeeping system for job-related injuries is widely accepted although underreporting is considered as substantial. In contrast, estimates of the incidence or prevalence of fatal and nonfatal work-related illnesses are very imprecise, partly because there is no adequate national surveillance system and partly because of complexities associated with discerning cause and effect. The economic burden of occupational injuries amounts to almost half the total cost of all injuries in the United States, and the cost of occupational illnesses is believed to exceed that attributable to injuries. For example,

including lost work days and reduced productivity, the costs of occupational skin diseases alone might reach $1 billion a year. The impact of occupational injuries, disabilities, and diseases spreads in ripples beyond the affected worker and employer to families and society at large in ways that are not easily measured or expressed in monetary terms. The effectiveness of OSHA's regulatory activities directed towards reducing occupational risks cannot be assessed in the absence of adequate national surveillance data.

RECOMMENDATION: To assess the effects of OSHA's regulations on workplace health and safety for the purpose of guiding NIOSH and OSHA research and regulatory priorities, Congress should direct NIOSH to strengthen its surveillance and intervention-effectiveness research and OSHA to expand its evaluation program.

RATIONALE

A substantial proportion of the estimated 60,000 worker fatalities each year is believed to result from occupational diseases associated with exposures to toxic substances and harmful physical agents. Many cases of fatal, chronic, and disabling occupational diseases develop over 10-30 years and are poorly counted by employer reporting or workers-compensation systems. For the cases that are reported, the attributable costs underestimate costs due to lost productivity and reduced earning potential, and such human values as reduced quality of life are not considered. The lost work day is an inadequate measure of the impact of chronic diseases. Without accurate information on the incidence and prevalence of occupational illnesses, the effect of a regulation on incidence or prevalence cannot be assessed. Without information on the effect of regulations, it is difficult to target research and regulatory priorities toward the exposures and illnesses of greatest concern.

Over the last 2 years, a comparative risk analysis for priority-setting has been conducted by OSHA with strong participation from NIOSH and many stakeholders. The product of that effort, OSHA's priority-planning process, is the identification of 18 emerging or persistent occupational-safety and occupational-health issues most in need of agency action, both regulatory and nonregulatory. The results were unveiled in December 1995; work has begun on their implementation. The agenda outlines regulatory priorities based on objective data, subjective judgment, and expert knowledge. Whether workplace interventions based on the identified priorities will have the desired effect on occupational illnesses, however, can be assessed and, hopefully, verified through an effective surveillance program.

In a similar process over the last year, NIOSH led 500 federal agencies, industries, associations, labor unions, academics, and private citizens in the development of the National Occupational Research Agenda. The agenda outlines priorities for the nation's public and private research in occupational safety and health. It is intended to increase the efficiency and effectiveness of such research by focusing efforts on the most important current and emerging scientific needs for improving the safety and health of workers. It is also an important step in efforts by NIOSH to engage in and promote extensive research coordination and collaboration among organizations and scientists throughout the public and private sectors. Risk assessment

itself was identified through testimony as a priority.

In both the OSHA and NIOSH priority-setting projects, information on the incidence and prevalence of occupational injuries and illnesses was used to the extent that they were available. However, both OSHA and NIOSH drew heavily on the expert judgment and experience of the stakeholders who participated in the open and iterative processes by which the final products were developed.

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FINDING 6.2.2: The Occupational Safety and Health Act institutionalized the clear separation of health research (NIOSH) and science-based policy decisions (OSHA). Although it is important that OSHA and NIOSH have distinct responsibilities, it is also critical that these interdependent organizations work closely together.

RECOMMENDATION: OSHA and NIOSH should focus on ways to facilitate effective collaboration so that OSHA's regulatory needs guide NIOSH's research efforts and NIOSH's contributions to OSHA are well-targeted toward OSHA's regulatory and science-policy needs, as well as towards serving private-sector worker-protection programs. Current programs focused on cooperation between the organizations should be strengthened.

RATIONALE

As the 1994 National Research Council report *Science and Judgment in Risk Assessment* emphasized, science-policy judgments made in the course of risk assessment would be improved if they were more clearly informed by a regulatory agency's priorities and goals in risk management. Protecting the integrity of risk assessment and building more productive linkages to risk management were both considered essential. OSHA and NIOSH have different responsibilities and play different roles in protecting worker health and safety, but they are clearly interdependent. NIOSH provides OSHA with scientific criteria and recommendations in support of OSHA's mandate to set health and safety standards. NIOSH identifies health-based exposure limits, and OSHA uses them to develop occupational standards that reflect feasibility considerations.

An interagency task force was formed to conduct the priority-planning process. There is an exchange of senior staff, who serve as full-time liaisons within the agencies' directors' offices. Because their risk-assessment and risk-management responsibilities are closely linked, it is important that they seek ways to ensure an effective interaction.

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FINDING 6.2.3: OSHA seems to have relied upon a case-by-case approach for performing risk assessment and risk characterization in support of risk-management policy decisions. Its 1980 "cancer policy" is rarely used and was written before the many scientific advances of the

1980s and 1990s. Its risk-management targets—for example, reducing cancer risk to less than one case per 1,000 workers exposed—might reflect the difficulty of demonstrating technical or economic feasibility at lower risk levels.

RECOMMENDATION: OSHA should publish, after appropriate public involvement and review, one or more sets of guidelines that lay out its scientific and policy defaults. The guidelines should, at a minimum, cover the following: an explicit rationale for choosing the defaults and an explicit standard for how and when to modify them, methods for assessing risk for noncancer health effects of concern in occupational settings, methods for quantifying and expressing uncertainty and individual variability in risk, and a statement of the magnitude of individual risk that it considers negligible for the various adverse health effects. The guidelines should help OSHA decide how extensive a risk assessment is needed in different situations. Finally, OSHA should explain and justify its actions when it evaluates or regulates a substance differently than other federal agencies that regulate the same substance.

RATIONALE

Risk-assessment guidelines have served EPA well over the years. OSHA has similar needs but its analyses are sufficiently different that it cannot simply adopt EPA's guidelines or the recommendations of *Science and Judgment in Risk Assessment* (NRC 1994a). In their testimony before the Commission, Adam Finkel, director of OSHA's Directorate of Health Standards Programs, and Frank White, vice president of Organization Resources Counselors, Inc., agreed that articulated risk-assessment guidance is urgently needed. They also agreed with the testimony of Frank Mirer, director of the Health and Safety Department of the International Union of United Auto Workers, that OSHA's risk-assessment procedures should not be uniform, but should be consistent with the magnitude of effect or controversy that a particular standard is likely to generate. To be useful, OSHA's guidelines must recognize that OSHA cannot treat each risk assessment with the same degree of rigor and detail, particularly as it seeks to make up the ground lost in a 1992 court decision vacating more than 400 permissible exposure limits (PELs). Because of the large number of PEL risk assessments that are needed and the fact that substances regulated via PELs will not be subject to the numerous ancillary provisions of OSHA's substance-specific rule-makings (such as medical surveillance and worker training), OSHA should outline a less-exhaustive risk-assessment template for this category of analysis.

6.3

Food and Drug Administration

The Food and Drug Administration (FDA) promotes and protects the public health by regulating a wide variety of consumer and medical-care products. FDA is responsible for ensuring that human food, animal feed, and cosmetics are safe and truthfully labeled; that human and animal drugs, medical devices, and biologics are safe, effective, and truthfully labeled; and that radiation from x-ray equipment and electronic products (such as television receivers and microwave ovens) does not exceed acceptable limits. FDA is now exercising its responsibility to protect minors from chemicals in cigarettes. Thus, a wide array of safety issues are considered in conjunction with a broad spectrum of benefits. FDA also conducts research on risk-assessment methods and mechanisms of adverse health effects. In this section, the Commission offers recommendations about food safety, drug approval, and dietary supplements.

FINDING 6.3.1: The Delaney clause of the Federal Food, Drug, and Cosmetic Act prohibits FDA approval of food additives (section 409) and color additives (section 721) that have been shown in appropriate studies to cause cancer in laboratory animals (or humans). Exactly what is covered by the Delaney clause is very complicated. Prohibition was an appropriate response to unknowns about cancer-causing chemicals when FFDCA was enacted in 1958, but it is inconsistent with modern analytic detection methods and current scientific knowledge.

RECOMMENDATION: The language of the Delaney clause should be modified to permit consideration of the quantitative risk that a covered food additive or color additive might pose, specifying that direct or indirect addition of carcinogens to foods should be prohibited to the extent needed to provide reasonable certainty of no harm, as is in keeping with well-established FDA statutory language.

RATIONALE

The Delaney clause, inserted in 1958 into section 409 of the FFDCA specifies that “no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal”; equivalent language in section 721 specifies that “a color additive shall be deemed unsafe . . .” In fact, definitions of food additives are extremely complicated. Excluded from the category of food additives under the Delaney clause are uses of substances generally recognized as safe (GRAS), ingredients sanctioned before 1958 (such as sodium nitrite and BHA in some uses), and pesticide residues on raw agricultural commodities. All intentionally added substances and uses not excluded are covered, such as artificial sweeteners and pesticides that concentrate in processed food. Color additives, covered separately from food additives, may be added to foods, drugs, cosmetics, and even devices. Indirect additions to

the food supply are covered by the Delaney clause, including chemicals that migrate into foods from packaging or other food-contact surfaces. Although FDA has been a leader in developing methods for quantitative risk assessment of carcinogens, under the prohibition of the Delaney clause the methods cannot be used. (See also the discussion in section 6.1.3 of this report about the inconsistencies between FIFRA and sections 408 and 409 of FFDCA in the case of pesticides.)

In 1962, Congress enacted an amendment to the Delaney clause known as the diethylstilbestrol (DES) proviso. This amendment permitted the use of carcinogenic compounds as animal-feed additives and veterinary drugs as long as "no residue of the additive shall be found by methods approved by the Secretary by regulation in any edible portion of the animals after slaughter or in any food such as milk or eggs yielded by or derived from living animals." To define no residue, FDA developed a quantitative, negligible-risk standard known as the sensitivity-of-method standard. The FDA commissioner is authorized to specify which analytic detection method should be used to characterize concentrations of additives. The methods chosen typically have a sensitivity corresponding to detection of a concentration associated with an upper-bound lifetime incremental cancer risk of one in a million (10^{-6}).

The Delaney clause does not define found to induce cancer and therefore does not invite exceptions for substances that induce tumors in rodents by mechanisms that are not relevant to human cancer risk (see section 3.1). However, even in 1958, Delaney required the FDA to determine whether evidence of carcinogenicity in animals had been obtained in "appropriate studies", with emphasis on feeding studies for obvious reasons of relevance. Because the clause focuses on the potentially carcinogenic properties of additives, it does not consider risks of other adverse health effects that can far outweigh risks of cancer, such as risks of developmental or neurologic toxicity, although those risks do get full attention from FDA under other authorities. Nevertheless, the requirement under the Delaney clause to reach a decision on animal carcinogenicity and appropriateness of studies makes a disproportionate claim on agency and petitioner resources, which might better be spread over investigations and reviews of all serious health effects and over decisions of whether any proposed uses of an additive would be deemed safe. Quantitative risk-assessment methods are applied routinely to determine acceptable concentrations of natural, unavoidable food contaminants (such as aflatoxin in peanuts and corn, or mercury in swordfish) or of trace contaminants of food and color additives, and to determine the urgency of regulatory actions.

To its credit, adoption of the Delaney clause called attention to substances that might cause cancer and to the importance of caution when knowledge is limited. The Commission has concluded from various testimony, however, that the direct impact of the Delaney clause on reducing cancer risks for the public has not been large, partly because most food-protection decisions are governed by other strong provisions of the food-safety laws and partly because the clause has been invoked decisively only a few times. Furthermore, FDA's efforts to regulate sodium nitrite in 1979 (under multiple provisions of FFDCA) highlighted the need to balance risks and benefits at different concentrations when a chemical has major health

benefits (in this case, prevention of botulism in stored meats).

Debate about the role of food additives and pesticide residues in relation to the role of other dietary factors that increase or decrease cancer risk led to the National Research Council report *Carcinogens and Anticarcinogens in the Human Diet* (NRC 1996b). That report concluded that calories, fat, and fiber are more important for overall cancer risk than individual food constituents, whether synthetic or naturally occurring.

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FINDING 6.3.2: Despite acceleration of the drug-approval process, especially for HIV-AIDS and cancer treatment agents, and despite providing guidance to pharmaceutical and biotechnology firms during various stages of drug development, FDA is often criticized by patient groups eager for access to new agents or agents approved in other countries. At the same time, FDA bears a heavy responsibility to assure the public that the risks of serious adverse effects have been fully investigated and properly evaluated by disinterested experts.

RECOMMENDATION: FDA should sustain its efforts to provide early guidance on appropriate studies and to complete reviews and necessary inspections expeditiously. Accelerated reviews and approvals should be linked to rigorous post-marketing surveillance. In keeping with its counterpart agencies in other countries, FDA should update criteria for toxicity-testing and clinical-trial protocols so that properly documented studies meeting those criteria in other countries can be used as evidence for FDA review. And FDA should continue to work with other countries to harmonize procedural and paperwork requirements, as well as the protocols. Such efforts should be broadened beyond HIV-AIDS and cancer treatment agents to other classes of therapies.

RATIONALE

There is an inevitable tension between careful premarketing assessment before regulatory approval of drugs, vaccines, and other medical products and the desire to make important advances in patient care available to patients. The Commission supports FDA efforts to accelerate the review process, use fee-based enhancement of FDA staff resources, and give guidance to firms and their clinical and biostatistical investigators. Moving towards accelerated reviews must be accompanied by requirements for strict postmarketing surveillance, perhaps including restriction of early prescribing rights to qualified and certified specialists who must closely study their patients' side effects and report them promptly.

In this global economy, FDA is building on many years of public and private international partnerships seeking harmonization of testing protocols and risk-assessment methods to make appropriate use of studies and documentation from other nations that meet mutually agreed-on regulatory standards. Nevertheless, approvals in other countries with different benefit and risk criteria and with different degrees of reliance on postmarketing surveillance cannot automatically lead to approval by FDA. More attention in this country to off-label use and

postmarketing surveillance of both benefits and risks would be desirable.

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FINDING 6.3.3: The Nutrition Labeling and Education Act of 1990 set up a framework for justifying health claims on food labels, including those for dietary supplements. This framework requires substantial scientific evidence and review and approval by FDA. FDA published the mandated regulations in January 1993 and approved several health claims. Soon thereafter, however, the Dietary Supplement Health and Education Act of 1994 (DSHEA) changed FDA's authority to regulate the safety and labeling of dietary supplements. The agency now has the burden of proving that a dietary supplement is adulterated before it can act to protect public health. DSHEA also created a presidential commission that was directed to reconsider what evidence would be necessary to make health claims for vitamins and other dietary supplements. Today, dietary supplements can carry FDA-approved health claims. DSHEA also permits manufacturers to make statements of nutritional support without prior approval from FDA. A Keystone Center Dialog report (1996) on health claims for foods and dietary supplements supported the 1990 act and the 1993 FDA regulations and made additional suggestions.

Recent evidence of hazards from herbal supplements promoted among young people for a "natural high" illustrates the consequences of allowing biologically active substances on the market without adequate evidence of safety. Also, evidence from clinical trials of lack of benefit of and probable harm from beta-carotene supplements in smokers at high risk of lung cancer and heart disease illustrate the importance of assuring that health claims are supported by sound science before they are used to promote the sale of products.

RECOMMENDATION: FDA's authority to require scientific evidence to justify manufacturers' claims of safety of and health benefits from nutritional supplements should be reaffirmed and strengthened.

RATIONALE

Vitamin supplements, herbs, and "natural" foods are increasingly marketed with claims of health benefits, reflecting preliminary data from epidemiologic analyses or medical testimonials. Evidence from clinical trails is rarely available. Since 1994, overwhelming evidence has been published that one of the most popular and most promising supplements, beta-carotene, previously considered anticarcinogenic, does not reduce risks of lung cancer and heart disease; instead, beta-carotene is associated with increases in those risks in people at high risk (ATBC 1994, Omenn et al. 1996). In light of the public's and scientists' desire to prevent cancer, heart disease, and other major diseases, we should strengthen the scientific basis of public-health advice, regulatory approval, and product marketing.

6.4

Department of Agriculture

The U.S. Department of Agriculture (USDA) Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) was established by the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. The office's primary role is to ensure that major human health, safety, environmental regulations proposed by USDA are based on sound scientific and economic analysis. A major regulation is one that is projected to have an incremental economic cost of at least $100 million per year. The office is responsible for providing technical assistance, for coordinating risk-analysis activities across USDA, that the statutory requirements of the act are met. This section offers several recommendations that should be considered as the office's activities take shape.

FINDING 6.4.1: USDA's Office of Risk Assessment and Cost Benefit Analysis (ORACBA) has the statutory authority to review a major regulation before it is submitted to the Secretary of Agriculture, but only at the end of the regulation-development procedure.

RECOMMENDATION: ORACBA should become involved in regulation development as soon as the impetus for a regulation is identified.

RATIONALE

Waiting until a regulation has been under development for a year or more and is virtually complete to determine whether it meets risk and cost criteria does not make sense. Considerations of context, risk, and cost should be included in the regulation-development process from the start and, to the extent that they are consistent with statute, should help guide it. Risk and cost evaluations performed only when a regulation is almost complete are unlikely to be useful because much time and resources will already have been invested in the outcome.

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FINDING 6.4.2: USDA has no formal procedure for external peer review of its risk assessments or economic analyses.

RECOMMENDATION: ORACBA should establish formal guidelines for peer review of the procedures, practices, and products of risk assessment and economic analysis at USDA.

RATIONALE

As noted in section 5.5 of this report, peer review is an essential part of the regulatory process. Peer review should encompass review of the raw technical data that underlie a risk assessment or benefit-cost analysis, the models and assumptions used and their interpretation, and how those data were cited in a regulatory decision. Involving independent peer reviewers in the regulatory process can help to clarify the objectives and scope of rule-making and verify the quality of the technical information considered. It can also ensure that the information evaluated at the start of the process has been used in a technically defensible manner. More detailed recommendations about the role of peer-review panels in regulatory decision-making are in section 5.5. When USDA's regulatory actions involve some types of pesticide or food-safety issues, it might be appropriate to coordinate their peer review with EPA or FDA.

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FINDING 6.4.3: In January 1993, pathogenic *E. coli* caused at least four deaths, dozens of cases of kidney failure in children, and over 600 illnesses in one outbreak linked to undercooked, contaminated ground beef. This toll would have been far greater had an excellent public-health science base and surveillance and investigation activity not been in place at the local and state health departments and the University of Washington's School of Public Health, which relied on modern genetic techniques for detecting and tracing contamination. Salmonella contamination of chicken and eggs has also led to fatal illnesses. Those and similar incidents focused public attention on the protection of our food supply from microbial contamination. However, the methods currently used by USDA to assess microbial risks for the purpose of evaluating and regulating food safety are rudimentary, conflicting, and based on inadequate data.

RECOMMENDATION: USDA should develop and improve methods for assessing microbial risks for food safety evaluation. It should also develop information and data-reporting requirements to gather data to support those risk assessments.

RATIONALE

A key responsibility of USDA, together with FDA, is protecting the nation's food supply from microbial contaminants. USDA's meat and poultry inspection program and FDA's food inspection program were not designed to prevent food-safety problems. Inspections involve visual reviews of operating procedures, with little knowledge of conditions prior to the inspection or ability to predict future conditions. Agencies and industries have been expanding their use of the concept of hazard analysis and critical control points (HACCP). Pathways for contamination are identified, controls are designed and installed, monitoring is supposed to be performed, and records are made available for audits. Problems are expected to stimulate a feedback to critical control points and control measures. This food-industry program is a counterpart to manufacturing aspects of responsible care in the chemical

industry. Combining this preventive approach with an effective public-health surveillance scheme could raise public confidence in the safety of our food supply domestically and help set an international standard for safe food. For example, beginning in 1995 all seafood exported to the European Community had to be produced under standards certified by the exporting country and accepted by the EC as equivalent to their HACCP standards. At the state level, HACCP plans are being used to update and unify ordinances regarding retail food handling and sanitation, together with such industry groups as the National Fisheries Institute, the National Food Processors Association, public-health agencies, and consumer groups. As emphasized by Michael Taylor, formerly of FDA and now at USDA, prevention's key elements are anticipation of the problems to be prevented and design of appropriate preventive methods. These require a useful knowledge base and continuous scientific progress from research on such topics as viable-but-not-cultural microorganisms, biofilms that harbor microorganisms shielded from sanitizing techniques, emerging foodborne pathogens, and conditions that affect the virulence (hazard) of potentially pathogenic microorganisms. Also, there is need for more information about food processing, packaging, and distribution techniques.

Risk assessment should play a key role in this activity, but methods of evaluating risks associated with microbial contaminants are in their developmental stages and require more rigorous application and evaluation. Many microbial-risk problems require the development of new methods and models. In addition, there are no databases on microbial diseases and risks comparable with those on chemical hazards. More detailed recommendations on the development of microbial risk-assessment methods are in section 3.6 of this report. Collaboration with the EPA Office of Water, whose Information Collection Rule establishing monitoring and data-reporting requirements for public water-supply systems might be a good model for a similar USDA rule, would be appropriate (see section 6.1.4).

6.5

Department of Energy

The Department of Energy (DOE) manages one of the largest environmental programs in the world, including 130 sites and facilities in over 30 states and territories, the legacies of the World War II and of the Cold War. The purpose of environmental management at DOE is to reduce health and safety risks associated with radioactive and hazardous waste and contamination resulting from the production, development, and testing of nuclear weapons. This section offers recommendations on the use of comparative risk for priority-setting and budgeting.

FINDING 6.5.1: The massive program of cleanup of nuclear-weapons production and waste sites has historically lacked a risk-based approach. Since late 1993, DOE has established a process that is committed to relating risks and risk reduction to budget and programmatic priorities. DOE's Environmental Management Program (DOE/EM) established six strategic goals: to address truly urgent risks, to ensure worker safety, to assume managerial and financial control, to become outcome-oriented, to focus on technology development, and to become more customer- and stakeholder-oriented. The effort is experimental and is a highly desirable input to the annual budget request and appropriation.

RECOMMENDATION: The 2½-year initiative of DOE/EM, stimulated by Congress, to learn to assess and manage the entire environmental program from a risk perspective should be continued and should be examined as a model for the EPA Superfund program (see section 6.1.2.4).

RATIONALE

The DOE sites are large, numerous, and complex; they include radioactive wastes, diverse chemical wastes, mixed radioactive and chemical wastes, and contaminated and dilapidated facilities, and they have special nuclear materials that need to be decommissioned. The program is one of the largest "discretionary" federal budget items, having grown from $2.3 billion in FY 1990 to $6.5 billion in FY 1994 before beginning a "down-sizing." It is complicated by signed agreements with numerous states and EPA (tri-party agreements) and signed agreements with American Indian nations that have treaty rights to large areas of particular sites. Those agreements, a legacy of the Bush Administration, used technical know-how at the time and empowered the states to make potent claims on federal responsibility. All parties acknowledge that there remain major uncertainties about the nature, extent, and remediability of major components of those sites, let alone a final selection of a permanent nuclear waste repository site.

DOE Secretary Hazel O'Leary, at Hanford Summit I in September 1993, committed the

department to complying with occupational and environmental requirements of sister federal agencies (OSHA and EPA) and to taking dramatic steps to override the 50-year history of secretive operation of the nuclear-weapons program. She and Assistant Secretary Thomas Grumbly called on the scientific community to join the effort with fresh ideas and capabilities. Grumbly reiterated that request at a National Research Council workshop commissioned by DOE to determine whether DOE needed to identify new institutional mechanisms to develop "objective, neutral, systematic, and iterative risk-based analysis" for DOE sites. Within 60 days, the Research Council committee issued *Building Consensus Through Risk Assessment*, supporting the DOE plan (NRC 1994b). That report highlighted the inclusion of cultural, socioeconomic, historical, and religious values in a new risk-based approach that incorporated public involvement at each step. Eventually, DOE funded the Consortium for Risk Evaluation with Stakeholder Participation (CRESP) and several smaller academic groups and consulting firms to work with all stakeholders, including DOE. Commissioners Goldstein and Omenn are among the founders and leaders of the consortium.

Simultaneous with this long-term institution-building, the conference report of the Energy and Water Development Appropriations Subcommittee for FY 1994 stated that DOE "needs to develop a mechanism for establishing priorities among competing clean-up requirements" and submit a report to Congress by June 30, 1995. DOE mobilized a major effort to describe and characterize its major activities on risk data sheets and submitted its summary of the results in *Risks and the Risk Debate: Searching for Common Ground, The First Step* (DOE 1995) in timely fashion. The DOE Environmental Management Advisory Board endorsed this draft risk report as an important first step in linking risk data with compliance considerations for use in budget decisions; it also recommended improvements in data quality, review, public involvement, and consistent interpretation of data in light of future land-use planning and long-term cost projections.

DOE/EM followed up in late 1995 and early 1996 by substantially reworking its risk-data-sheet approach and then integrating it with the EM 1998 budget process. Risk data sheets now rank the significance of each DOE activity in terms of seven considerations, the first three of which are specific risk factors: public safety and health, site-personnel safety and health, environmental protection, compliance with applicable laws and regulations, mission impact, reduction of the "mortgage"of remaining cleanup obligations, and social, economic, and cultural impacts. For every activity, each of the seven considerations is ranked high, medium, or low; definitions of those evaluations are somewhat uncomfortable and cumbersome. DOE regional and site managers develop the rankings and data to support the 1400 risk data sheets but substantial efforts to involve stakeholders in both criteria definition and risk-data-sheet quality assurance are evolving. The entire risk-ranking process is being reviewed externally and internally at DOE. Congress, this Commission, and most others regard this unprecedented process as a worthy start. DOE should balance the need to formalize the process quickly with the need to keep it fluid until its elements became coherent. Many suggestions for improvement are being assessed for incorporation.

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FINDING 6.5.2: DOE sites represent an important opportunity to evaluate potential risks to workers from remediation activities.

RECOMMENDATION: DOE should actively develop means to integrate and evaluate worker risk into their decision-making process concerning the choice and timing of remediation options.

RATIONALE

EPA has seldom evaluated worker risks at Superfund sites. This omission results partly because workers often do not reside locally and therefore do not participate in the risk-assessment or remedial decision, and partly because workers receive a benefit—their jobs and their pay—which does not accrue to the community at risk. In contrast, DOE sites are generally in remote communities where the remediation workers are or become part of the community at risk, during what is expected to be longer, sustained efforts at remediation in comparison to Superfund sites. The employment provided by the need to remediate is considered a benefit to the community.

Integrating community and remediation-worker risks provides challenges. For example, the risk to those who remove hazardous chemicals and radioactive wastes occurs only between the time that the work begins and the end of their lifetimes, while the risk to community members extends into future generations if remediation does not occur or is ineffective or insufficient. In addition, much worker risk is due to injuries and occurs in early adulthood, while much of the risk of mortality in the community is due to cancer or other diseases occurring late in life. Integrating analyses of worker- and community-health risks thus presents the challenges of accounting for different health and safety effects, different periods of exposure occurring at different times in a lifetime, and different perceptions about the risks and benefits of remediation options and cleanup standards.

6.6

Department of Defense

The Defense Environmental Restoration Program was established by Congress in 1984 to evaluate and remediate sites that were contaminated as a result of Department of Defense (DOD) activities. The Commission received testimony from the office of the deputy under secretary of defense for environmental security about DOD's strategy for implementing a relative-risk-based ranking procedure for setting priorities among the sites that were to be addressed. This section discusses very briefly DOD's efforts to establish remediation priorities among its contaminated sites.

FINDING 6.6: The contaminated sites that DOD is legally bound to clean up are not all sites that pose the worst risks to health or the environment. DOD has developed a relative-risk ranking procedure to facilitate priority-setting among contaminated sites.

RECOMMENDATION: DOD should continue its efforts to establish risk-based remediation priorities among its contaminated sites in collaboration with community advisory groups.

RATIONALE

Listing procedures for the National Priority List establish entire DOD installations as single sites for the purpose of listing. DOD installations are generally large and varied, however, with locations of potentially high risk and locations of potentially low risk within a single installation. Since 1984, DOD has identified almost 20,000 potentially contaminated sites on some 1,700 current installations and about 8,000 potentially contaminated sites at formerly used installations in the United States. Given the large number and diversity of DOD's contaminated sites, a means to focus remedial activity that is consistent with relative risks to health and the environment was needed.

To assess relative risks at sites to help in the sequencing of remedial work, DOD developed the Relative Risk Site Evaluation Concept. The concept categorizes sites as of high, medium, or low risk on the basis of three factors: a hazard factor (a combined measure of contaminant concentrations in a given environmental medium), a migration-pathway factor (a measure of movement or potential movement of contaminants away from the original source), and a receptor factor (an indication of the potential for human or ecological contact with site contamination). A site's category can change because of new or additional information or as a result of cleanup activities. As in the Commission's risk-management framework, the rankings are performed in collaboration with community advisory groups at the sites. In practice, decisions about which sites should be addressed first include considerations in addition to the rankings, such as regulatory-agreement status and public health

recommendations. A special consideration with regard to cleanup practices and community involvement arises at sites on the base closure list.

DOD's ranking procedure does not involve actual assessments of health risks, nor does it address the decision of whether work is necessary at a site. The procedure only provides relative-risk information for use in determining the sequence in which sites will be addressed.

References

American Industrial Health Council (AIHC). 1993. Ecological Risk Assessment: Sound Science Makes Good Business Sense. Washington, DC

Association of Bay Area Governments (ABAG). 1978. Environmental Management Plan for the San Francisco Bay Area. Berkeley, CA

Albert, R.E. 1994. Carcinogen risk assessment in the U.S. Environmental Protection Agency. Critical Reviews in Toxicology 24:74-85

Arrow, K.J., Cropper, M.L., Eads, G.C., Hahn, R.W., Lave, L.B., Noll, R.G., Portney, P.R., Russell, M., Schmalensee, R., Smith, V.K., and Stavins, R.N. 1996. Benefit-Cost Analysis in Environmental, Health, and Safety Regulation. A Statement of Principles. Sponsored by The Annapolis Center, the American Enterprise Institute, and Resources for the Future

ATBC Cancer Prevention Study Group. 1994. The effect of vitamin E and beta carotene on the incidence of lung cancer and other cancers in male smokers. New England Journal of Medicine 330:1029-1035

Calkins, D.R., Dixon, R.L., Gerber, C.R., Zarin, D., and Omenn, G.S. 1980. Identification, characterization, and control of potential human carcinogens: a framework for federal decision-making. Journal of the National Cancer Institute 61:169-175

Carnegie Commission on Science, Technology, and Government. 1993. Risk and the Environment. Improving Regulatory Decision-Making. New York, NY

Chess, C., Salomone, K.L., Hance. B.J., and Saville, A. 1995. Results of a national symposium on risk communication: next steps for government agencies. Risk Analysis 15:115-125

Cohen, S.M., Cano, M., Garland, E.M., St. John, M., and Arnold, L.L. Urinary and urothelial effects of sodium salts in male rats. Carcinogenesis 16:343-348

Colburn, T., Myers, J.P., and Dumanski, D. 1996. Our Stolen Future. C. Dutton: New York, NY

Council for Excellence in Government. 1996. National Public Opinion Survey. Prepared by Peter Hart and Robert Teeter, Inc. Washington, DC

Crump, K.S., Clewell, H.J., and Anderson, M.E. 1996. Cancer and non-cancer risk

assessment should be harmonized. Biological Effects of Low Level Exposures Newsletter. (in press)

Davis, D.L. and Bradlow, H.L. 1995. Can environmental estrogens cause breast cancer? Scientific American, October issue, pp. 166-172

Economic Report of the President. 1996. Transmitted to the Congress February 1996 together with the Annual Report of the Council of Economic Advisers. U.S. Government Printing Office: Washington, DC

Eisenberg, J.N., Seto, E.Y.W., Olivieri, A.W., and Spear, R.C. 1996a. Quantifying water pathogen risk in an epidemiological framework. Risk Analysis (in press)

Eisenberg, J.N., Olivieri, A.W., Thompson, K., Seto, E.Y.W., and Konnan, J.I. 1996b. An approach to microbial risk assessment. American Water Works Association and Water Environment Federation. WaterReuse 96 Conference Proceedings. San Diego, CA

Falk, H.L. and Kotin, P.T.S. 1964. Inhibition of carcinogenesis. The effects of polycyclic hydrocarbons and related compounds. Archives of Environmental Health 9:169-179

Faustman, E.M. and Omenn, G.S. 1995. Risk Assessment. Chapter 4. In: C.D. Klaassen, ed. Casarett and Doull's Toxicology. The Basic Science of Poisons. Fifth Edition. McGraw-Hill: New York

Flamm, W.G. and Lorentzen, R.J. 1988. Quantitative Risk Assessment (QRA): A Special Problem in the Approval of New Products. In: C.R. Cothern, M.A. Mehlman, and W.L. Marcus, eds. Risk Assessment and Risk Management of Industrial and Environmental Chemicals. Princeton Scientific Publishing Co., Inc.: Princeton, NJ

Goldman, L.R. 1995. Environmental risk assessment and national policy: keeping the process fair, effective, and affordable. University of Cincinnati Law Review 63:1533-1551

Goldstein, B. 1990. The problem with the margin of safety: toward the concept of protection. Risk Analysis 10:7-10

Gorman, R.W. and Wallingford, K.M. 1989. The NIOSH Approach to Conducting Indoor Air Quality Investigations in Office Buildings. In: N.L. Nagda and J.P. Harper, eds. Design and Protocol for Monitoring Indoor Air Quality. ASTM STP 1002. American Society for Testing and Materials. Philadelphia, PA

Groten, J.P., Kuper, F.C., Schoen, E.D., Van Bladeren, P.J., and Feron, V.J. 1994. Subacute toxicity studies of a combination of nine chemicals in rats. Presented at the Second Annual Health Effects Research Laboratory Symposium: Chemical Mixtures and Quantitative Risk Assessment. Raleigh, NC

Haas, C.N., Rose, J.B., Gerba, C., and Regli, S. 1993. Risk assessment of virus in drinking water. Risk Analysis 13:545-552

Haas, C.N. 1983. Estimation of risk due to low doses of microorganisms: a comparison of alternative methodologies. American Journal of Epidemiology 55:573-582

Harris, J.E. Diesel emissions and lung cancer. Risk Analysis 3:83-100

Health Effects Institute (HEI). 1996. The Potential Health Effects of Oxygenates Added to Gasoline: A Review of the Current Literature. A Special Report. Cambridge, MA

Ikeda, M. 1988. Multiple exposure to chemicals. Regulatory Toxicolology and Pharmacology 8:414-421

Jonker, D., Woutersen, R.A., Van Bladeren, P.J., Til, H.P., and Feron, V.J. 1990. Four-week oral toxicity study of a combination of eight chemicals in rats: Comparison with the toxicity of the individual compounds. Food and Chemical Toxicolology 28:623-631

Jonker, D., Woutersen, R.A., Van Bladeren, P.J., Til, H.P., and Feron, V.J. 1993. Subacute (4-wk) oral toxicity of a combination of four nephrotoxins in rats: Comparison with the toxicity of the individual compounds. Food and Chemical Toxicolology 31:125-136

Karr, J.R. 1991. Biological integrity: a long-neglected aspect of water resource management. Ecological Applications. February, pp. 66-84

Keystone Center. 1996. The Keystone National Policy Dialogue on Food, Nutrition, and Health. Keystone, CO and Washington, DC

Lave, L.B., Ennever, F.K., Rosenkranz, H.S., and Omenn, G.S. 1988. Information value of the rodent bioassay. Nature 336:631-633

Lewtas, J. 1993. Complex mixtures of air pollutants: characterizing the cancer risk of polycyclic organic matter. Environmental Health Perspectives 100:211-218

McCallum, D.B. and Santos, S. 1995. Participation and Persuasion. A Communications Perspective on Risk Management. In: R. Kollara et al., eds. Risk Assessment and Management Handbook. McGraw Hill Inc. New York

McClain, R.M. 1994. Mechanistic considerations in the regulation and classification of chemical carcinogens. In: F.N. Kotsonis, M. Mackey, and J. Hijele, eds. Nutritional Toxicology. Raven Press Ltd.: New York, NY

McGinnis, J.M. and Foege, W.H. 1993. Actual causes of death in the United States. Journal of the American Medical Association 270:2207-2212

McLachlan, J. and Korach, K., eds. 1995. Estrogens in the Environment, III. Environmental Health Perspectives: Supplement 7. National Institute of Environmental Health Sciences. Research Triangle Park, NC

Melnick, R.L., Kohn, M.C., and Portier, C.J. 1996. Implications for risk assessment of suggested nongenotoxic mechanisms of chemical carcinogenesis. Environmental Health Perspectives 104S:123-134

Minard, R. and Jones, K. 1993. State Comparative Risk Projects: A Force for Change. The Northeast Center for Comparative Risk. South Royalton, VT

Morgan, M.G., Fischoff, B., Bostrom, A., Lave, L., and Atman, C.J. 1992. Communicating risk to the public. Environmental Science and Technology. 26:2048-2056

National Academy of Public Administration (NAPA). 1995. Setting Priorities, Getting Results: A New Direction for EPA. Washington, DC

National Commission on the Environment. 1992. Choosing a Sustainable Future. World Wildlife Federation. Washington, DC

National Research Council (NRC). 1983. Risk Assessment in the Federal Government: Managing the Process. National Academy Press. Washington, DC

National Research Council (NRC). 1988. Complex Mixtures. National Academy Press. Washington, DC

National Research Council (NRC). 1989. Improving Risk Communication. National Academy Press. Washington, DC

National Research Council (NRC). 1993. Pesticides in the Diets of Infants and Children. National Academy Press. Washington, DC

National Research Council (NRC). 1994a. Science and Judgment in Risk Assessment. National Academy Press. Washington, DC

National Research Council (NRC). 1994b. Building Consensus Through Risk Assessment. National Academy Press. Washington, DC

National Research Council (NRC). 1996a. Understanding Risk. Informing Decisions in a Democratic Society. National Academy Press. Washington, DC

National Research Council (NRC). 1996b. Carcinogens and Anticarcinogens in the Human Diet: A Comparison of Naturally Occurring and Synthetic Substances. National Academy Press. Washington, DC

National Cancer Institute (NCI). 1984. SEER Program: Cancer Incidence and Mortality in the United States: 1973-1981. National Institutes of Health. Department of Health and Human Services. Washington, DC

Neumann, D.A. and Olin, S.S. 1995. Urinary bladder carcinogenesis: a working group approach to risk assessment. Food and Chemical Toxicolology 33:701-704

Office of Technology Assessment (OTA). 1995. Gauging Control Technology and Regulatory Impact in Occupational Safety and Health—An Appraisal of OSHA's Analytic Approach. OTA-ENV635. Washington, DC

Omenn, G.S. 1982. Predictive identification of the hypersusceptible individual. Journal of Occupational Medicine 24:369-374

Omenn, G.S. and Faustman, E. (in press) Risk Assessment. In: R. Detels, W. Holland, J. McEwen, and G.S. Omenn, eds. Oxford Textbook of Public Health. Third Edition. Oxford University Press. Oxford, UK

Omenn, G.S. and Lave, L.B. 1988. Scientific and cost-effectiveness criteria in selecting batteries of short-term tests. Mutation Research 205:41-49

Omenn, G.S., Stuebbe, S., and Lave, L.B. 1995. Predictions of rodent carcinogenicity testing results: interpretation in light of the Lave-Omenn value-of-information model. Molecular Carcinogenesis 14:37-45

Omenn, G.S., Goodman, G.E., Thornquist, M.D., Balmes, J., Cullen, M.R., Glass, A., Keogh, J.P., Meyskens, J.L., Valanis, B., Williams, J.H., Barnhart, S., and Hammar, S. 1996. Effects of a combination of beta carotene and vitamin A on lung cancer and cardiovascular disease. New England Journal of Medicine 334:1150-1155

Organization for Economic Cooperation and Development (OECD). 1996. Environmental Performance Reviews: United States. Paris, France

President's Council on Sustainable Development (PCSD). 1996. Sustainable America. A New Consensus for Prosperity, Opportunity, and a Healthy Environment for the Future. Washington, DC

Richards, M. 1993. Siting Industrial Facilities. Lessons from the Social Science Literature. Presented at the Fifth Annual International Conference of the Society for the Advancement of Socio-Economics. Environmental Decision-Making. New York City. March 26-28

Rowe, R., Lang, C., Chestnut, L., Latimer, D., Rae, D., Bernow, S., and White, D. 1995. The New York State Externalities Study. Oceana Publications, Inc. Dobbs Ferry, NY

Rozman, K.K., Kerecsen, L., Viluksela, M.K., Österle, D., Deml, E., Viluksela, M., Stahl, B.U., Greim, H., and Doull, J. 1996. A toxicologist's view of cancer risk assessment. Drug Metabolism Reviews 28:29-52

Ruckelshaus, W.D. 1995. Stopping the Pendulum. The Environmental Forum. Nov./Dec., pp. 25-29

Rulis, A.M. 1989. Establishing a Threshold of Regulation. In: J.J. Bonin and D.E. Stevenson, eds. Risk Asssessment in Setting National Priorities. Plenum Publishing Corp.

Sandman, P.M. 1993. Responding to community outrage: strategies for effective risk communication. American Industrial Hygiene Association. Fairfax, VA

Schmähl, D., Schmidt, K.G., and Habs, M. 1977. Syncarcinogenic Action of Polycyclic Aromatic Hydrocarbons in Automobile Exhaust Gas Condensates. In: U. Mohr, D. Schmähl, and L. Tomatis, eds. Air Pollution and Cancer in Man. IARC Publication 16. World Health Organization. Lyon, France

Slovic, P. 1987. Perception of risk. Science 236:280-285

Upton, A.U. (in press) Health Risk from Radiation. In: R. Detels, W. Holland, J. McEwen, and G.S. Omenn, eds. Oxford Textbook of Public Health. Third Edition. Oxford University Press. Oxford, UK

U.S. Department of Energy (DOE). 1995. Risks and the Risk Debate: Searching for Common Ground. Office of Environmental Management. Washington, DC

U.S. Environmental Protection Agency (EPA). 1987a. The Total Exposure Assessment Methodology (TEAM) Study. Summary and Analysis. EPA/600/6-87/002a. Office of Acid Deposition, Enviornmental Monitoring and Quality Assurance. Washington, DC

U.S. Environmental Protection Agency (EPA). 1987b. Unfinished Business: A Comparative Assessment of Environmental Problems. Office of Policy Analysis. Washington, DC

U.S. Environmental Protection Agency (EPA). 1990. Reducing Risk: Setting Priorities and Strategies For Environmental Protection. Science Advisory Board. SAB-EC-90-0021. Washington, DC

U.S. Environmental Protection Agency. 1991. Report of the EPA Peer Review Workshop on $Alpha_{2u}$-Globulin: Association with Renal Toxicity and Neoplasia in the Male Rat. EPA/625/3-91/021. Risk Assessment Forum. Washington, DC

U.S. Environmental Protection Agency (EPA). 1992a. Guidelines for Exposure Assessment.

U.S. Environmental Protection Agency (EPA). 1992b. Framework for Ecological Risk Assessment. EPA/630/R-92/001. Risk Assessment Forum. Washington, DC

U.S. Environmental Protection Agency (EPA). 1992c. Safeguarding the Future: Credible Science, Credible Decisions. Report of the Expert Panel on the Role of Science at EPA. EPA/600/9-91/050. Washington, DC

U.S. Environmental Protection Agency (EPA). 1992d. A Tiered Modeling Approach for Assessing the Risks Due to Sources of Hazardous Air Pollutants. Office of Air Quality Planning and Standards. Research Triangle Park, NC

U.S. Environmental Protection Agency (EPA). 1993. A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective. Risk Assessment Forum. EPA630-R-92-005. Washington, DC

U.S. Environmental Protection Agency (EPA). 1994. Peer Review and Peer Involvement at the U.S. Environmental Protection Agency. Office of the Administrator. Washington, DC

U.S. Environmental Protection Agency (EPA). 1995a. Guidance for Risk Characterization. Science Policy Council. Washington, DC

U.S. Environmental Protection Agency (EPA). 1995b. Memorandum: New Policy on Evaluating Health Risks to Children. Office of the Administrator. Washington, DC

U.S. Environmental Protection Agency (EPA). 1995c. An Introduction to Environmental Accounting as a Business Management Tool: Key Concepts and Terms. EPA 742-R-001. Office of Prevention, Pesticides and Toxic Substances. Washington, DC

U.S. Environmental Protection Agency (EPA). 1996. Proposed Guidelines for Carcinogen Risk Assessment. (EPA/600/P-92/003C). Office of Research and Development. Washington, DC

Van Horn, C.E. 1988. Breaking the Environmental Gridlock. The Eagleton Institute of Politics. Rutgers University. New Brunswick, NJ

Weinstein, N.D., Kolb, K., and Goldstein, B.D. 1996. Using time intervals between expected events to communicate risk magnitudes. Risk Analysis (in press)